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## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<b>(51) International Patent Classification <sup>7</sup> :</b>  <b>A61K 31/00</b>	<b>A2</b>	<b>(11) International Publication Number:</b> <b>WO 00/32176</b>  <b>(43) International Publication Date:</b> 8 June 2000 (08.06.00)
<b>(21) International Application Number:</b> PCT/US99/28080  <b>(22) International Filing Date:</b> 24 November 1999 (24.11.99)  <b>(30) Priority Data:</b> 60/110,127 27 November 1998 (27.11.98) US 60/124,087 11 March 1999 (11.03.99) US 60/126,056 23 March 1999 (23.03.99) US  <b>(71) Applicant:</b> HOLLIS-EDEN PHARMACEUTICALS, INC. [US/US]; Suite 200, 9333 Genesee Avenue, San Diego, CA 92121 (US).  <b>(72) Inventors:</b> AHLEM, Clarence, Nathaniel; 8960 Montrose Way, San Diego, CA 92122 (US). FRINCKE, James, Martin; P.O. Box 927420, San Diego, CA 92192 (US). PRENDERGAST, Patrick, T.; Baybush, Straffan, County Kildare (IE). THADIKONDA, Krupakar, Paul; 7510 Boxberry Terrace, Gaithersburg, MD 20879 (US).  <b>(74) Agent:</b> HUNT, Dale, C.; Knobbe, Martens, Olson & Bear, LLP, 16th floor, 620 Newport Center Drive, Newport Beach, CA 92660 (US).		<b>(81) Designated States:</b> AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).  <b>Published</b> <i>Without international search report and to be republished          upon receipt of that report.</i>
<b>(54) Title:</b> USE OF 17-KETOSTEROID COMPOUNDS AND DERIVATIVES, METABOLITES AND PRECURSORS THEREOF IN TREATMENT OF TOXOPLASMOSIS AND IN THE TREATMENT OF CRYPTOSPORIDIOSIS  <b>(57) Abstract</b>  The invention provides the use of 17-ketosteroid compounds, e.g., 16 $\alpha$ -bromoepiandrosterone, as well as derivatives, metabolites and precursors of such compounds, and pharmaceutically acceptable salts of any of these compounds, collectively defined herein as the "compounds of the present invention", to treat or prevent Toxoplasmosis or Cryptosporidiosis in patients in need of such treatment or prophylaxis. The formula (1) compounds can also be used to ameliorate or reduce one or more symptoms associated with such infections.		

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**USE OF 17-KETOSTEROID COMPOUNDS AND DERIVATIVES,  
METABOLITES AND PRECURSORS THEREOF IN TREATMENT OF  
TOXOPLASMOSIS AND IN THE TREATMENT OF CRYPTOSPORIDIOSIS**

## 5 BACKGROUND OF THE INVENTION

The present invention is directed to the use of 17-ketosteroid compounds, as well as derivatives, metabolites and precursors of such compounds, and pharmaceutically acceptable salts of any of these compounds, collectively defined herein as the "compounds of the present invention" in treatment of toxoplasmosis and/or in treatment of cryptosporidiosis. The present invention is also directed to the use of such compounds in combination with one or more additional compound (as described herein) in such treatments. The present invention is further directed to the use of such compounds (or combinations of compounds) for the manufacture of pharmaceutical formulations for treatment of such conditions.

Cryptosporidium is an intestinal parasite that is the etiologic agent of cryptosporidiosis.

15 This parasite is a protozoan that has been found in humans and animals, and has been found to cause severe diarrhea (sometimes fatal). Cryptosporidium has been found to be extremely resistant to many known antibiotics. Persons with normal immune systems can suffer from cryptosporidiosis, which is the apparent cause of many cases of diarrhea, and such persons usually recover within two weeks. Persons with serious immune deficiency, such as AIDS patients, may

20 never recover from Cryptosporidiosis. This disease can spread from person to person or from animals to persons, and the incubation period appears to be two weeks or less.

The *Toxoplasma gondii* protozoan is the etiologic agent of Toxoplasmosis. This sporozoa is an intracellular parasite that resides inside macrophages and has evolved a mechanism to avoid being killed by intracellular oxygen, metabolites and lysosomal enzymes.

25       The live parasite, *Toxoplasma gondii*, when ingested by a macrophage, forms a membrane bound vesicle called a phagosome. This phagosome containing the Toxoplasma parasite can inhibit the fusion of lysosomes to the phagosome, which would cause its digestion and elimination. However, if dead Toxoplasma parasites are ingested by macrophages, the phagosome thus resulting cannot prevent lysosome fusion, and parasite digestion. It is the function of the

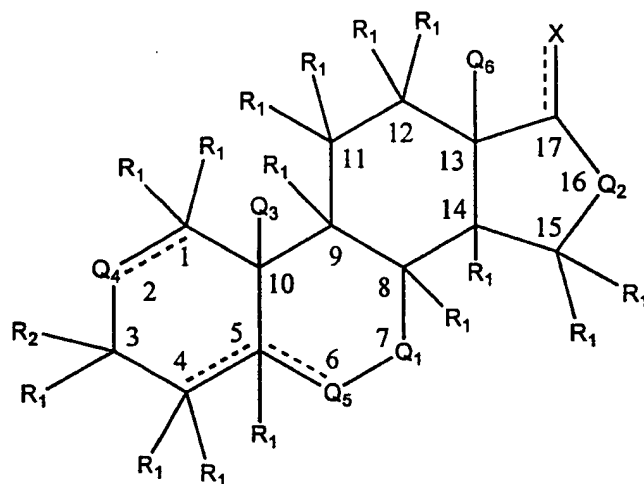
30       biosynthetic machinery of the parasite to synthesize molecules that block the ability of the lysosome to fuse with the Toxoplasma phagosome.

A number of steroid compounds and their uses have been described. See, e.g., U.S. patent numbers 4956355, 5859000, 4268441, 4666898, 5837269, 5827841, 5811418, 5824313, 5686438, 5635496, 5587369, 5583126, 5562910, 5532230, 5518725, 5736537, 5843932, 5837700, 5824671, 5807849, 5798347, 5780460, 5776923, 5728688, 5610150, 5593981, 5372996, 5110810, 5807848.

5707983, 5641766, 5585371, 5506223, 5424463, 5296481, 5292730, 5776921, 5641768, 5559107, 5478566, 5461042, 5407684, 5387583, 5277907, 5206008, 5077284, 5162198, 5660835, 5527789, 5756482, 5709878, 5804576, 5744462, 5714481, 5700793, 5696106, 5656621, 5175154, 5157031, 5028631, 5001119, 4898694, 5824668, 5710143, 5795880, 5527788, 5591736, 5861390 and PCT  
 5 publication numbers WO 98/05338, WO 95/21617, WO 98/50040, WO 98/50041 and WO 97/48367.

## SUMMARY OF THE INVENTION

In accordance with one aspect of the present invention, it now has been discovered that toxoplasmosis and cryptosporidiosis may be effectively treated with compounds (or  
 10 pharmaceutically acceptable salts thereof) of the following formula 1 (and metabolites, analogs and precursors thereof):



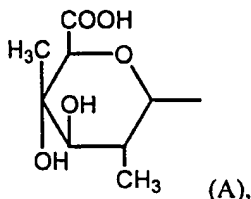
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wherein

- Q<sub>1</sub> is -C(R<sub>1</sub>)<sub>2</sub>- or -C(O)-;
- 15 Q<sub>2</sub> is -C(R<sub>1</sub>)<sub>2</sub>-, -C(R<sub>1</sub>)(Y)-, -C(Y)- or -CH<sub>2</sub>-CH<sub>2</sub>-;
- Q<sub>3</sub> is -H or -C(R<sub>1</sub>)<sub>3</sub>-;
- Q<sub>4</sub> is -C(R<sub>1</sub>)<sub>2</sub>-, -C(O)-, hydroxyvinylidene (-CH(CH=CHOH)-) or methyl methylene (-CH(CH)<sub>3</sub>-);
- Q<sub>5</sub> is -C(R<sub>1</sub>)<sub>2</sub>- or -C(O)-;
- 20 X and Y independently are -OH, -H, lower alkyl (e.g., C<sub>1-6</sub> alkyl), -O-C(O)-R<sub>5</sub>, -C(O)-OR<sub>5</sub>, halogen (i.e., -F, -Cl, -Br or -I) or =O;
- each R<sub>1</sub> independently is -H, -F, -Cl, -Br, -I, -OH, C<sub>1-6</sub> alkoxy, or C<sub>1-6</sub> alkyl;
- R<sub>2</sub> is -H, -OH, -F, -Cl, -Br, -I, C<sub>1-6</sub> alkyl, C<sub>1-6</sub> alkoxy, -OR<sub>3</sub>, an ester (e.g., -O-C(O)-R<sub>4</sub> or -C(O)-O-R<sub>4</sub>), a thioester (e.g., -O-C(S)-R<sub>4</sub> or -C(S)-O-R<sub>4</sub>), a thioacetal (e.g., -S-C(O)-R<sub>4</sub> or -C(O)-S-R<sub>4</sub>), a sulfate ester (e.g., -O-S(O)(O)-O-R<sub>4</sub>), a sulfonate ester (e.g., -O-S(O)-O-R<sub>4</sub>) or a
- 25

carbamate (e.g., -O-C(O)-NH-R<sub>4</sub> or -NH-C(O)-O-R<sub>4</sub>) or R<sub>2</sub>, together with the R<sub>1</sub> that is bonded to the same carbon atom is =O;

R<sub>3</sub> is -S(O)(O)-OM, -S(O)(O)-O-CH<sub>2</sub>-CH(O-C(O)-R<sub>6</sub>)-CH<sub>2</sub>-O-C(O)-R<sub>6</sub>,  
-P(O)(O)-O-CH<sub>2</sub>-CH(O-C(O)-R<sub>7</sub>)-CH<sub>2</sub>-O-C(O)-R<sub>7</sub>, a glucuronide group of structure (A)



5 or R<sub>3</sub> is C<sub>1-18</sub> alkyl, C<sub>2-18</sub> alkenyl, C<sub>2-18</sub> alkynyl, a C<sub>1-18</sub> ester or a C<sub>1-18</sub> thioester, where any of the foregoing C<sub>1-18</sub> or C<sub>2-18</sub> moieties are optionally substituted at one or more hydrogen atoms with one or more independently selected -OR<sup>PR</sup>, (including -OH), -NHR<sup>PR</sup>, (including -NH<sub>2</sub>) or -SR<sup>PR</sup>, (including -SH) groups, or R<sub>3</sub> is a C<sub>1-18</sub> fatty acid, C<sub>2-10</sub> alkynyl, (J)<sub>n</sub>-phenyl-C<sub>1-5</sub>-alkyl,  
10 (J)<sub>n</sub>-phenyl-C<sub>2-5</sub>-alkenyl;

R<sub>4</sub> is -H, a protecting group, optionally substituted C<sub>1-18</sub> alkyl, optionally substituted C<sub>2-18</sub> alkenyl, optionally substituted C<sub>2-18</sub> alkynyl, optionally substituted aryl, optionally substituted aryl-C<sub>1-6</sub> alkyl, optionally substituted aryl-C<sub>2-6</sub> alkenyl, optionally substituted aryl-C<sub>2-6</sub> alkynyl, optionally substituted heterocycle-C<sub>1-6</sub> alkyl, optionally substituted C<sub>2-6</sub> alkenyl-heterocycle,  
15 optionally substituted C<sub>2-6</sub> alkynyl-heterocycle or an optionally substituted heterocycle, where any of the foregoing moieties are optionally substituted at one, two, three, four, five or more carbon or hydrogen atoms with one or more independently selected -O-, -S-, -NR<sup>PR</sup> (including -NH-), -NH-C(O)-, -OR<sup>PR</sup> (including -OH), -NHR<sup>PR</sup> (including -NH<sub>2</sub>), -SR<sup>PR</sup> (including -SH), =O, =S, =N-OH, -CN, -NO<sub>2</sub>, -F, -Cl, -Br or -I groups or atoms;

20 each R<sub>5</sub> independently is straight or branched C<sub>1-14</sub> alkyl;

each R<sub>6</sub> independently is straight or branched C<sub>1-14</sub> alkyl;

each R<sub>7</sub> independently is straight or branched C<sub>1-14</sub> alkyl or a glucuronide group of structure (A);

each R<sup>PR</sup> independently is -H or an independently selected protecting group;

25 n is 0, 1, 2 or 3;

each J independently is -F, -Cl, -Br, -I, C<sub>1-4</sub> alkyl, C<sub>1-4</sub> alkenyl, C<sub>1-4</sub> alkoxy, carboxy, nitro, sulfate, sulfonyl, a C<sub>1-6</sub> carboxyl ester or a C<sub>1-6</sub> sulfate ester;

M is hydrogen, sodium, -S(O)(O)-O-CH<sub>2</sub>-CH(O-C(O)-R<sub>6</sub>)-CH<sub>2</sub>-O-C(O)-R<sub>6</sub>, -P(O)(O)-O-CH<sub>2</sub>-CH(O-C(O)-R<sub>7</sub>)-CH<sub>2</sub>-O-C(O)-R<sub>7</sub> or a glucuronide group of structure (A); and

30 the dotted lines in formula 1 represent an optional double bond, provided that there are not double bonds at both the 4-5 and 5-6 positions and provided that when a double bond is present,

zero or 1 R<sub>1</sub> group is bonded to carbon atoms at the 1-, 2-, 4-, 5-, 6- or 17 positions so that these carbon atoms are tetravalent; and

the salts, stereoisomers, positional isomers, metabolites, analogs, precursors, hydrates, tautomers, ionized forms and solvates thereof. The formula 1 compounds are collectively referred herein to as the "compounds of the invention" or the "compounds of the present invention".

Accordingly, the present invention provides a method for treating these parasitic infections which comprises administering to an afflicted host a therapeutically effective amount of a compound (or a pharmaceutically acceptable salt thereof) having the structure of formula 1, or a metabolite or precursors thereof, as defined herein.

#### DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

As used herein and unless otherwise stated or implied by context, the following terms have the meanings defined here.

A "patient" or "subject" means a human or animal. Usually the animal is a vertebrate such as a primate, rodent, domestic animal or game animal. Primates include chimpanzees, cynomologous monkeys, spider monkeys, and macaques, e.g., *Rhesus*. Rodents include mice, rats, woodchucks, ferrets, rabbits and hamsters. Domestic and game animals include cows, horses, pigs, deer, bison, buffalo, felines, e.g., domestic cat, canines, e.g., dog, avians, e.g., chicken, emu, ostrich, and fish, e.g., trout, catfish and salmon. Patient or subject includes any subset of the foregoing, e.g., all of the above, but excluding one or more groups or species such as humans, primates or rodents.

"Alkyl" as used herein, unless stated to the contrary, is a C<sub>1</sub>-C<sub>18</sub> hydrocarbon containing 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17 or 18 carbon atoms in the form of normal, secondary, tertiary, cyclic or mixed structures. Examples are -CH<sub>3</sub>, -CH<sub>2</sub>CH<sub>3</sub>, -CH<sub>2</sub>CH<sub>2</sub>CH<sub>3</sub>, -CH(CH<sub>3</sub>)<sub>2</sub>, -CH<sub>2</sub>CH<sub>2</sub>CH<sub>2</sub>CH<sub>3</sub>, -CH<sub>2</sub>CH(CH<sub>3</sub>)<sub>2</sub>, -CH(CH<sub>3</sub>)CH<sub>2</sub>CH<sub>3</sub>, -C(CH<sub>3</sub>)<sub>3</sub>, -CH<sub>2</sub>CH<sub>2</sub>CH<sub>2</sub>CH<sub>2</sub>CH<sub>3</sub>, -CH(CH<sub>3</sub>)CH<sub>2</sub>CH<sub>2</sub>CH<sub>3</sub>, -CH(CH<sub>2</sub>CH<sub>3</sub>)<sub>2</sub>, -C(CH<sub>3</sub>)<sub>2</sub>CH<sub>2</sub>CH<sub>3</sub>, -CH(CH<sub>3</sub>)CH(CH<sub>3</sub>)<sub>2</sub>, -CH<sub>2</sub>CH<sub>2</sub>CH(CH<sub>3</sub>)<sub>2</sub>, -CH<sub>2</sub>CH(CH<sub>3</sub>)CH<sub>2</sub>CH<sub>3</sub>, -CH<sub>2</sub>C(CH<sub>3</sub>)<sub>3</sub>, -CH<sub>2</sub>CH<sub>2</sub>CH<sub>2</sub>CH<sub>2</sub>CH<sub>2</sub>CH<sub>3</sub>, -CH(CH<sub>3</sub>)CH<sub>2</sub>CH<sub>2</sub>CH<sub>2</sub>CH<sub>3</sub>, -CH(CH<sub>2</sub>CH<sub>3</sub>)(CH<sub>2</sub>CH<sub>2</sub>CH<sub>3</sub>), -C(CH<sub>3</sub>)<sub>2</sub>CH<sub>2</sub>CH<sub>2</sub>CH<sub>3</sub>, -CH(CH<sub>3</sub>)CH(CH<sub>3</sub>)CH<sub>2</sub>CH<sub>3</sub>, -CH(CH<sub>3</sub>)CH<sub>2</sub>CH(CH<sub>3</sub>)<sub>2</sub>, -C(CH<sub>3</sub>)(CH<sub>2</sub>CH<sub>3</sub>)<sub>2</sub>, -CH(CH<sub>2</sub>CH<sub>3</sub>)CH(CH<sub>3</sub>)<sub>2</sub>, -C(CH<sub>3</sub>)<sub>2</sub>CH(CH<sub>3</sub>)<sub>2</sub>, -CH(CH<sub>3</sub>)C(CH<sub>3</sub>)<sub>3</sub>,

cyclopropyl, cyclobutyl, cyclopropylmethyl, cyclopentyl, cyclobutylmethyl, 1-cyclopropyl-1-ethyl, 2-cyclopropyl-1-ethyl, cyclohexyl, cyclopentylmethyl, 1-cyclobutyl-1-ethyl, 2-cyclobutyl-1-ethyl, 1-cyclopropyl-1-propyl, 2-cyclopropyl-1-propyl, 3-cyclopropyl-1-propyl, 2-cyclopropyl-2-propyl, and 1-cyclopropyl-2-propyl.

"Alkenyl" as used herein, unless stated to the contrary, is C<sub>2</sub>-C<sub>18</sub> hydrocarbon comprising 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17 or 18 carbon atoms in the form of normal,

secondary, tertiary, cyclic or mixed structures and comprising 1, 2, 3 or more double bonds between adjacent carbon atoms. Examples are  $-\text{CH}=\text{CH}_2$ ,  $-\text{CH}=\text{CHCH}_3$ ,  $-\text{CH}_2\text{CH}=\text{CH}_2$ ,  $-\text{C}(\text{=CH}_2)(\text{CH}_3)$ ,  $-\text{CH}=\text{CHCH}_2\text{CH}_3$ ,  $-\text{CH}_2\text{CH}=\text{CHCH}_3$ ,  $-\text{CH}_2\text{CH}_2\text{CH}=\text{CH}_2$ ,  $-\text{CH}=\text{C}(\text{CH}_3)_2$ ,  $-\text{CH}_2\text{C}(\text{=CH}_2)(\text{CH}_3)$ ,  $-\text{C}(\text{=CH}_2)\text{CH}_2\text{CH}_3$ ,  $-\text{C}(\text{CH}_3)=\text{CHCH}_3$ ,  $-\text{CH}(\text{CH}_3)\text{CH}=\text{CH}_2$ ,  $-\text{C}=\text{CHCH}_2\text{CH}_2\text{CH}_3$ ,  $-\text{CHCH}=\text{CHCH}_2\text{CH}_3$ ,  $-\text{CHCH}_2\text{CH}=\text{CHCH}_3$ ,  $-\text{CHCH}_2\text{CH}_2\text{CH}=\text{CH}_2$ ,  $-\text{C}(\text{=CH}_2)\text{CH}_2\text{CH}_2\text{CH}_3$ ,  $-\text{C}(\text{CH}_3)=\text{CH}_2\text{CH}_2\text{CH}_3$ ,  $-\text{CH}(\text{CH}_3)\text{CH}=\text{CHCH}_3$ ,  $-\text{CH}(\text{CH}_3)\text{CH}_2\text{CH}=\text{CH}_2$ ,  $-\text{CH}_2\text{CH}=\text{C}(\text{CH}_3)_2$ , 1-cyclopent-1-enyl, 1-cyclopent-2-enyl, 1-cyclopent-3-enyl, 1-cyclohex-1-enyl, 1-cyclohex-2-enyl, and 1-cyclohex-3-enyl.

“Alkynyl” as used herein, unless stated to the contrary, is  $\text{C}_2$ - $\text{C}_{18}$  hydrocarbon comprising 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17 or 18 carbon atoms in the form of normal, secondary, tertiary, cyclic or mixed structures and comprising 1, 2, 3 or more triple bonds between adjacent carbon atoms. Examples are  $-\text{CCH}$ ,  $-\text{CCCH}_3$ ,  $-\text{CH}_2\text{CCH}$ ,  $-\text{CCCH}_2\text{CH}_3$ ,  $-\text{CH}_2\text{CCCH}_3$ ,  $-\text{CH}_2\text{CH}_2\text{CCH}$ ,  $-\text{CH}(\text{CH}_3)\text{CCH}$ ,  $-\text{CCCH}_2\text{CH}_2\text{CH}_3$ ,  $-\text{CH}_2\text{CCCH}_2\text{CH}_3$ ,  $-\text{CH}_2\text{CH}_2\text{CCCH}_3$  and  $-\text{CH}_2\text{CH}_2\text{CH}_2\text{CCH}$ .

“Halogen” or “halo” means fluorine (-F), chlorine (-Cl), bromine (-Br) or iodine (-I) and if more than one halogen is referred to (e.g., two or more variable groups may be a halogen), each halogen is independently selected.

“Steroid nucleus” means 4 fused rings having the formula 1 structure.

“PEG” means an ethylene glycol polymer that contains about 20 to about 2000000 linked monomers, typically about 50-1000 linked monomers, usually about 100-300. Polyethylene glycols include PEGs containing various numbers of linked monomers, e.g., PEG20, PEG30, PEG40, PEG60, PEG80, PEG100, PEG115, PEG 200, PEG 300, PEG400, PEG500, PEG600, PEG 1000, PEG1500, PEG2000, PEG 3350, PEG4000, PEG4600, PEG5000, PEG6000, PEG8000, PEG11000, PEG12000, PEG2000000 and any mixtures thereof.

An “excipient” or a “carrier” means a component or an ingredient that is acceptable in the sense of being compatible with the other ingredients of compositions or formulations as disclosed herein and not overly deleterious to the patient or animal to which the formulation is to be administered. As used here, excipients and carriers include liquids, including benzyl benzoate, cottonseed oil, N,N-dimethylacetamide, a  $\text{C}_{2-12}$  alcohol (e.g., ethanol), glycerol, peanut oil, a PEG, vitamin E, poppyseed oil, propylene glycol, safflower oil, sesame oil, soybean oil and vegetable oil. Excipients, as used herein may exclude solvents such as chloroform, dioxane or DMSO. Excipients comprise one or more components typically used in the pharmaceutical formulation arts, e.g., fillers, binders, disintegrants and lubricants.



Unless otherwise specified, expressions that refer to “a formula 1 compound”, a “compound of the invention”, a “compound of the present invention” and the like mean compositions or methods, e.g., methods to treat a *Toxoplasmosis* or a *Cryptosporidiosis* infection as disclosed herein, where one or more than one formula 1 compound is present, typically 1, 2, 3 or 4, usually 1.

“Alcohol” as used herein, includes excipients, means an alcohol that comprises a C<sub>1-12</sub> alkyl moiety substituted at one or more hydrogen atoms with one or more hydroxyl groups, usually one, two or three. Alcohols include, e.g., ethanol, *n*-propanol, *i*-propanol, *n*-butanol, *i*-butanol, *s*-butanol, *t*-butanol, *n*-pentanol, *i*-pentanol, *n*-hexanol, cyclohexanol, *n*-heptanol, *n*-octanol, *n*-nonanol, *n*-decanol and benzyl alcohol. The carbon atoms in alcohols can be straight, branched or cyclic. Alcohol includes any subset of the foregoing, e.g., C<sub>2-4</sub> alcohols (alcohols having 2, 3 or 4 carbon atoms).

“Ester” means a moiety that comprises a -C(O)-O- structure. Typically, esters as used here comprise an organic moiety containing about 1-50 carbon atoms (e.g., about 2-12 carbon atoms) and 0 to about 10 independently selected heteroatoms (e.g., O, S, N, P, Si), where the organic moiety is bonded to a formula 1 steroid nucleus at R<sup>2</sup> through the -C(O)-O- structure, e.g., organic moiety-C(O)-O-steroid or organic moiety-O-C(O)-steroid. The organic moiety usually comprises one or more of any of the organic groups described above, e.g., C<sub>1-20</sub> alkyl moieties, C<sub>2-20</sub> alkenyl moieties, C<sub>2-20</sub> alkynyl moieties, aryl moieties, C<sub>2-9</sub> heterocycles or substituted derivatives of any of these, e.g., comprising 1, 2, 3, 4 or more substituents, where each substituent is independently chosen. Typical substitutions for hydrogen or carbon atoms in these organic groups include 1, 2, 3, 4 or more, usually 1, 2, or 3 -O-, -S-, -NR<sup>PR</sup>- (including -NH-), -C(O)-, =O, =S, -N(R<sup>PR</sup>)<sub>2</sub> (including -NH<sub>2</sub>), -C(O)OR<sup>PR</sup> (including -C(O)OH), -OC(O)R<sup>PR</sup> (including -O-C(O)-H), -OR<sup>PR</sup> (including -OH), -SR<sup>PR</sup> (including -SH), -NO<sub>2</sub>, -CN, -NHC(O)-, -C(O)NH-, -OC(O)-, -C(O)O-, -O-A<sub>8</sub>, -S-A<sub>8</sub>, -C(O)-A<sub>8</sub>, -OC(O)-A<sub>8</sub>, -C(O)O-A<sub>8</sub>, =N-, -N=, =N-OH, -OPO<sub>3</sub>(R<sup>PR</sup>)<sub>2</sub>, -OSO<sub>3</sub>H<sub>2</sub> or halogen moieties or atoms, where each R<sup>PR</sup> is -H, an independently selected protecting group or both R<sup>PR</sup> together comprise a protecting group, and A<sub>8</sub> is C<sub>1-8</sub> alkyl, C<sub>2-8</sub> alkenyl, C<sub>2-8</sub> alkynyl, C<sub>1-4</sub> alkyl-aryl (e.g., benzyl), aryl (e.g. phenyl) or C<sub>0-4</sub> alkyl-C<sub>2-9</sub> heterocycle. Substitutions are independently chosen. The organic moiety includes compounds defined by the R<sub>4</sub> variable. The organic moieties exclude obviously unstable moieties, e.g., -O-O-, except where such unstable moieties are transient species that one can use to make a compound with sufficient chemical stability for the one or more of the uses described herein. The substitutions listed above are typically substituents that one can use to replace one or more carbon atoms, e.g., -O- or -C(O)-, or one or more hydrogen atom, e.g., halogen, -NH<sub>2</sub>, -OH or =O.

“Thioester” means a moiety that comprises a -C(S)-O- structure. Typically, thioesters as used here comprise an organic moiety containing about 1-50 carbon atoms (e.g., about 2-12 carbon atoms) and 0 to about 10 heteroatoms (e.g., O, S, N, P, Si), where the organic moiety is bonded to a formula 1 steroid nucleus at R<sup>2</sup> through the -C(S)-O- structure, e.g., organic moiety-C(S)-O-steroid or organic moiety-O-C(S)-steroid. The organic moiety usually comprises one or more of any of the organic groups described above, e.g., C<sub>1-20</sub> alkyl moieties, C<sub>2-20</sub> alkenyl moieties, C<sub>2-20</sub> alkynyl moieties, aryl moieties, C<sub>2-9</sub> heterocycles or substituted derivatives of any of these, e.g., comprising 1, 2, 3, 4 or more substituents, where each substituent is independently chosen. Typical substitutions for hydrogen or carbon atoms in these organic groups include 1, 2, 3, 4 or more, usually 1, 2, or 3 -O-, -S-, -NR<sup>PR</sup>- (including -NH-), -C(O)-, =O, =S, -N(R<sup>PR</sup>)<sub>2</sub> (including -NH<sub>2</sub>), -C(O)OR<sup>PR</sup> (including -C(O)OH), -OC(O)R<sup>PR</sup> (including -O-C(O)-H), -OR<sup>PR</sup> (including -OH), -SR<sup>PR</sup> (including -SH), -NO<sub>2</sub>, -CN, -NHC(O)-, -C(O)NH-, -OC(O)-, -C(O)O-, -O-A<sub>8</sub>, -S-A<sub>8</sub>, -C(O)-A<sub>8</sub>, -OC(O)-A<sub>8</sub>, -C(O)O-A<sub>8</sub>, =N-, -N=, =N-OH, -OPO<sub>3</sub>(R<sup>PR</sup>)<sub>2</sub>, -OSO<sub>3</sub>H<sub>2</sub> or halogen moieties or atoms, where each R<sup>PR</sup> is -H, an independently selected protecting group or both R<sup>PR</sup> together comprise a protecting group, and A<sub>8</sub> is C<sub>1-8</sub> alkyl, C<sub>2-8</sub> alkenyl, C<sub>2-8</sub> alkynyl, C<sub>1-4</sub> alkyl-aryl (e.g., benzyl), aryl (e.g. phenyl) or C<sub>0-4</sub> alkyl-C<sub>2-9</sub> heterocycle. Substitutions are independently chosen. The organic moiety includes compounds defined by the R<sub>4</sub> variable. The organic moieties exclude obviously unstable moieties, e.g., -O-O-, except where such unstable moieties are transient species that one can use to make a compound with sufficient chemical stability for the one or more of the uses described herein. The substitutions listed above are typically substituents that one can use to replace one or more carbon atoms, e.g., -O- or -C(O)-, or one or more hydrogen atom, e.g., halogen, -NH<sub>2</sub>, -OH or =O.

“Thioacetal” means a moiety that comprises a -C(O)-S- structure. Typically, thioacetals as used here comprise an organic moiety containing about 1-50 carbon atoms (e.g., about 2-12 carbon atoms) and 0 to about 10 heteroatoms (e.g., O, S, N, P, Si), where the organic moiety is bonded to a formula 1 steroid nucleus at R<sup>2</sup> through the -C(O)-S- structure, e.g., organic moiety-C(O)-S-steroid or organic moiety-S-C(O)-steroid. The organic moiety is as described above for thioesters.

“Carbamate” means an organic moiety as described for ester that comprises 1, 2, 3, 4 or more -O-C(O)NR<sup>PR</sup>- structures where R<sup>PR</sup> is -H, a protecting group or an organic moiety as described for ester. Typically, carbamate groups as used here comprise an organic moiety containing about 1-50 carbon atoms (e.g., about 2-12 carbon atoms) and 0 to about 10 heteroatoms (e.g., O, S, N, P, Si), where the organic moiety is bonded to a formula 1 steroid nucleus at R<sup>2</sup> through the -O-C(O)-NR<sup>PR</sup>- structure, e.g., organic moiety-NR<sup>PR</sup>-C(O)-O-steroid or organic moiety-O-C(O)-NR<sup>PR</sup>-steroid. The organic moiety is as described above for thioesters.

“Sulfate ester” means a moiety that comprises a -O-S(O)(O)-O- structure. Typically, sulfate esters as used here comprise an organic moiety containing about 1-50 carbon atoms (e.g., about 2-12 carbon atoms) and 0 to about 10 heteroatoms (e.g., O, S, N, P, Si), where the organic moiety is bonded to a formula 1 steroid nucleus at R<sup>2</sup> through the -O-S(O)(O)-O- structure, e.g., organic moiety-O-S(O)(O)-O-steroid. The organic moiety is as described above for thioesters.

“Sulfite ester” means a moiety that comprises a -O-S(O)-O- structure. Typically, sulfite esters as used here comprise an organic moiety containing about 1-50 carbon atoms (e.g., about 2-12 carbon atoms) and 0 to about 10 heteroatoms (e.g., O, S, N, P, Si), where the organic moiety is bonded to a formula 1 steroid nucleus at R<sup>2</sup> through the -O-S(O)-O- structure, e.g., organic moiety-O-S(O)-O-steroid. The organic moiety is as described above for thioesters.

The compositions disclosed herein optionally comprise salts of the formula 1 compounds that comprise an ionizable moiety or a polar moiety. As used herein, “salts” include complexes that comprise moieties of opposite charge. Ionizable moieties include -O-S(O)(O)-OH or a -NH<sub>2</sub> group at R<sub>2</sub> and polar moieties include -OH. Salts include pharmaceutically acceptable salts that comprise, for example, an uncharged moiety or a monovalent anion moiety or a monovalent cation moiety. Salts include compounds derived by combination of appropriate anions such as inorganic acids. Suitable acids include those having sufficient acidity to form a stable salt, preferably acids of low toxicity. For example, one may form invention salts from acid addition of certain inorganic acids, e.g., HF, HCl, HBr, HI, H<sub>2</sub>SO<sub>4</sub>, H<sub>3</sub>PO<sub>4</sub>, to basic centers, typically amines that may be present in formula 1 compounds. Or one may use certain organic acids, e.g., organic sulfonic acids, organic carboxylic acids in the same manner. Exemplary organic sulfonic acids include C<sub>6-16</sub> aryl sulfonic acids, C<sub>6-16</sub> heteroaryl sulfonic acids and C<sub>1-16</sub> alkyl sulfonic acids such as phenyl,  $\alpha$ -naphthyl,  $\beta$ -naphthyl, (*S*)-camphor, methyl, ethyl, *n*-propyl, *i*-propyl, *n*-butyl, *s*-butyl, *i*-butyl, *t*-butyl, pentyl and hexyl sulfonic acids. Exemplary organic carboxylic acids include C<sub>1-16</sub> alkyl, C<sub>6-16</sub> aryl carboxylic acids and C<sub>4-16</sub> heteroaryl carboxylic acids such as acetic, glycolic, lactic, pyruvic, malonic, glutaric, tartaric, citric, fumaric, succinic, malic, maleic, hydroxymaleic, benzoic, hydroxybenzoic, phenylacetic, cinnamic, salicylic and 2-phenoxybenzoic. Salts also include the invention compound salts with one or more amino acids. Many amino acids are suitable, especially the naturally occurring amino acids found as protein components, although the amino acid typically is one bearing a side chain with a basic or acidic group, e.g., lysine, arginine or glutamic acid, or a neutral group such as glycine, serine, threonine, alanine, isoleucine, or leucine. Salts are usually biologically compatible or pharmaceutically acceptable or non-toxic, particularly for mammalian cells. Salts that are biologically toxic are generally used as synthetic intermediates for making other invention compounds.

Heterocycle. "Heterocycle" or "heterocyclic" includes by way of example and not limitation these heterocycles described in Paquette, Leo A.; "Principles of Modern Heterocyclic Chemistry" (W. A. Benjamin, New York, 1968), particularly Chapters 1, 3, 4, 6, 7, and 9; "The Chemistry of Heterocyclic Compounds, A series of Monographs" (John Wiley & Sons, New York, 1950 to present), in particular Volumes 13, 14, 16, 19, and 28; and *J. Am. Chem. Soc.* 1960, 82:5566; and U.S. patents 5763483 and 5811450, all of which are incorporated herein by reference.

Examples of heterocycles include by way of example and not limitation pyridyl, thiazolyl, tetrahydrothiophenyl, sulfur oxidized tetrahydrothiophenyl, pyrimidinyl, furanyl, thienyl, pyrrolyl, pyrazolyl, imidazolyl, tetrazolyl, benzofuranyl, thianaphthalenyl, indolyl, indolenyl, quinolynyl, isoquinolynyl, benzimidazolyl, piperidinyl, 4-piperidonyl, pyrrolidinyl, 2-pyrrolidonyl, pyrrolinyl, tetrahydrofuranyl, tetrahydroquinolynyl, tetrahydroisoquinolynyl, decahydroquinolynyl, octahydroisoquinolynyl, azocinyl, triazinyl, 6H-1,2,5-thiadiazinyl, 2H,6H-1,5,2dithiazinyl, thienyl, thianthrenyl, pyranyl, isobenzofuranyl, chromenyl, xanthenyl, phenoxathiinyl, 2H-pyrrolyl, isothiazolyl, isoxazolyl, pyrazinyl, pyridazinyl, indolizynyl, isoindolyl, 3H-indolyl, 1H-indazolyl, purinyl, 4H-quinolizynyl, phthalazinyl, naphthyridinyl, quinoxalynyl, quinazolynyl, cinnolynyl, pteridinyl, 4aH-carbazolyl, carbazolyl,  $\beta$ -carbolinyl, phenanthridinyl, acridinyl, pyrimidinyl, phenanthrolinyl, phenazinyl, phenothiazinyl, furazanyl, phenoxazinyl, isochromanyl, chromanyl, imidazolidinyl, imidazolynyl, pyrazolidinyl, pyrazolynyl, piperazinyl, indolynyl, isoindolynyl, quinuclidinyl, morpholynyl, oxazolidinyl, benzotriazolyl, benzisoxazolyl, oxindolyl, benzoxazolynyl, and isatinoyl.

By way of example and not limitation, carbon bonded heterocycles are bonded at position 2, 3, 4, 5, or 6 of a pyridine, position 3, 4, 5, or 6 of a pyridazine, position 2, 4, 5, or 6 of a pyrimidine, position 2, 3, 5, or 6 of a pyrazine, position 2, 3, 4, or 5 of a furan, tetrahydrofuran, thiofuran, thiophene, pyrrole or tetrahydropyrrole, position 2, 4, or 5 of an oxazole, imidazole or thiazole, position 3, 4, or 5 of an isoxazole, pyrazole, or isothiazole, position 2 or 3 of an aziridine, position 2, 3, or 4 of an azetidine, position 2, 3, 4, 5, 6, 7, or 8 of a quinoline or position 1, 3, 4, 5, 6, 7, or 8 of an isoquinoline. Still more typically, carbon bonded heterocycles include 2-pyridyl, 3-pyridyl, 4-pyridyl, 5-pyridyl, 6-pyridyl, 3-pyridazinyl, 4-pyridazinyl, 5-pyridazinyl, 6-pyridazinyl, 2-pyrimidinyl, 4-pyrimidinyl, 5-pyrimidinyl, 6-pyrimidinyl, 2-pyrazinyl, 3-pyrazinyl, 5-pyrazinyl, 6-pyrazinyl, 2-thiazolyl, 4-thiazolyl, or 5-thiazolyl.

By way of example and not limitation, nitrogen bonded heterocycles are bonded at position 1 of an aziridine, azetidine, pyrrole, pyrrolidine, 2-pyrroline, 3-pyrroline, imidazole, imidazolidine, 2-imidazoline, 3-imidazoline, pyrazole, pyrazoline, 2-pyrazoline, 3-pyrazoline, piperidine, piperazine, indole, indoline, 1H-indazole, position 2 of a isoindole, or isoindoline, position 4 of a

morpholine, and position 9 of a carbazole, or  $\beta$ -carboline. Typically, nitrogen bonded heterocycles include 1-aziridyl, 1-azetetyl, 1-pyrrolyl, 1-imidazolyl, 1-pyrazolyl, and 1-piperidinyl.

"Heteroaryl" means an aromatic ring or two or more fused rings that contain one or more aromatic rings where the ring or fused rings comprise 1, 2, 3 or more heteroatoms, usually oxygen (-O-), nitrogen (-NX-) or sulfur (-S-) where X is -H, a protecting group or C<sub>1-6</sub> alkyl, usually -H. Examples are as described for heterocycle.

Protecting groups. Various groups that the formula 1 compounds may comprise include, e.g., substituted alkyl groups, substituted alkenyl groups, esters or substituted heterocycles, which can contain one or more reactive moieties such as hydroxyl, or thiol. Intermediates used to make formula 1 compounds may be protected as is apparent in the art. Noncyclic and cyclic protecting groups and corresponding cleavage reactions are described in "Protective Groups in Organic Chemistry", Theodora W. Greene (John Wiley & Sons, Inc., New York, 1991, ISBN 0-471-62301-6) (hereafter "Greene"). In the context of the present invention, these protecting groups are groups that can be removed from the molecule of the invention without irreversibly changing the covalent bond structure or oxidation/reduction state of the remainder of the molecule. For example, the protecting group, -X, that is bonded to a -OX or -NHX group can be removed to form -OH or -NH<sub>2</sub>, respectively, without affecting other covalent bonds in the molecule. At times, when desired, more than one protecting group can be removed at a time, or they can be removed sequentially. In compounds of the invention containing more than one protecting group, the protecting groups are the same or different.

Protecting groups are intended to be removed by known procedures, although it will be understood that the protected intermediates fall within the scope of this invention. The removal of the protecting group may be arduous or straightforward, depending upon the economics and nature of the conversions involved. In general, one will use a protecting group with exocyclic amines or with carboxyl groups during synthesis of a formula 1 compound. For most therapeutic applications amine groups should be deprotected. Protecting groups commonly are employed to protect against covalent modification of a sensitive group in reactions such as alkylation or acylation. Ordinarily, protecting groups are removed by, e.g. hydrolysis, elimination or aminolysis. Thus, simple functional considerations will suffice to guide the selection of a reversible or an irreversible protecting group at a given locus on the invention compounds. Suitable protecting groups and criteria for their selection are described in T.W. Greene and P.G.M. Wuts, Eds. "Protective Groups in Organic Synthesis" 2nd edition, Wiley Press, at pps. 10-142, 143-174, 175-223, 224-276, 277-308, 309-405 and 406-454, which is incorporated herein by reference.

Determination of whether a group is a protecting group is made in the conventional manner, e.g., as illustrated by Kocienski, Philip J.; "*Protecting Groups*" (Georg Thieme Verlag

Stuttgart, New York, 1994) (hereafter "Kocienski"), Section 1.1, page 2, and Greene Chapter 1, pages 1-9; and U.S. patent 5763483 and 5811450, all of which are incorporated herein by reference. In particular, a group is a protecting group if when, based on mole ratio, 90% of that protecting group has been removed by a deprotection reaction, no more than 50%, preferably 25%,  
5 more preferably 10%, of the deprotected product molecules of the invention have undergone changes to their covalent bond structure or oxidation/reduction state other than those occasioned by the removal of the protecting group. When multiple protecting groups of the same type are present in the molecule, the mole ratios are determined when all of the groups of that type are removed. When multiple protecting groups of different types are present in the molecule, each type of  
10 protecting group is treated (and the mole ratios are determined) independently or together with others depending on whether the deprotection reaction conditions pertinent to one type are also pertinent to the other types present. In one embodiment of the invention, a group is a protecting group if when, based on mole ratio determined by conventional techniques, 90% of that protecting group has been removed by a conventional deprotection reaction, no more than 50%, preferably  
15 25%, more preferably 10%, of the deprotected product molecules of the invention have undergone irreversible changes to their covalent bond structure or oxidation/reduction state other than those occasioned by the removal of the protecting group. Irreversible changes require chemical reactions (beyond those resulting from aqueous hydrolysis, acid/base neutralization or conventional separation, isolation or purification) to restore the covalent bond structure or oxidation/reduction  
20 state of the deprotected molecule of the invention.

Protecting groups are also described in detail together with general concepts and specific strategies for their use in Kocienski, Philip J.; "Protecting Groups" (Georg Thieme Verlag Stuttgart, New York, 1994), which is incorporated by reference in its entirety herein. In particular Chapter 1, Protecting Groups: An Overview, pages 1-20, Chapter 2, Hydroxyl Protecting Groups,  
25 pages 21-94, Chapter 3, Diol Protecting Groups, pages 95-117, Chapter 4, Carboxyl Protecting Groups, pages 118-154, Chapter 5, Carbonyl Protecting Groups, pages 155-184, Chapter 6, Amino Protecting Groups, pages 185-243, Chapter 7, Epilog, pages 244-252, and Index, pages 253-260, are incorporated with specificity in the context of their contents. More particularly, Sections 2.3 Silyl Ethers, 2.4 Alkyl Ethers, 2.5 Alkoxyalkyl Ethers (Acetals), 2.6 Reviews (hydroxy and thiol  
30 protecting groups), 3.2 Acetals, 3.3 Silylene Derivatives, 3.4 1,1,3,3-Tetraisopropylidisiloxanylidene Derivatives, 3.5 Reviews (diol protecting groups), 4.2 Esters, 4.3 2,6,7-Trioxabicyclo[2.2.2]octanes [OBO] and Other Ortho Esters, 4.4 Oxazolines, 4.5 Reviews (carboxyl protecting groups), 5.2 O,O-Acetals, 5.3 S,S-Acetals, 5.4 O,S-Acetals, 5.5 Reviews (carbonyl protecting groups), 6.2 N-Acyl Derivatives, 6.3 N-Sulfonyl Derivatives, 6.4 N-Sulfonyl  
35 Derivatives, 6.5 N-Alkyl Derivatives, 6.6 N-Silyl Derivatives, 6.7 Imine Derivatives, and 6.8

Reviews (amino protecting groups), are each incorporated with specificity where protection/deprotection of the requisite functionalities is discussed. Further still, the tables "Index to the Principal Protecting Groups" appearing on the inside front cover and facing page, "Abbreviations" at page xiv, and "reagents and Solvents" at page xv are each incorporated in their entirety herein at this location.

Typical hydroxy protecting groups are described in Greene at pages 14-118 and include Ethers (Methyl); Substituted Methyl Ethers (Methoxymethyl, Methylthiomethyl, t-Butylthiomethyl, (Phenyldimethylsilyl)methoxymethyl, Benzyloxymethyl, p-Methoxybenzyloxymethyl, (4-Methoxyphenoxy)methyl, Guaiacolmethyl, t-Butoxymethyl, 4-Pentenylloxymethyl, Siloxymethyl, 2-Methoxyethoxymethyl, 2,2,2-Trichloroethoxymethyl, Bis(2-chloroethoxy)methyl, 2-(Trimethylsilyl)ethoxymethyl, Tetrahydropyranyl, 3-Bromotetrahydropyranyl, Tetrahydrothiopyranyl, 1-Methoxycyclohexyl, 4-methoxytetrahydropyranyl, 4-Methoxytetrahydrothiopyranyl, 4-Methoxytetrahydrothiopyranyl S,S-Dioxido, 1-[(2-Chloro-4-methyl)phenyl]-4-methoxypiperidin-4-yl, 1,4-Dioxan-2-yl, Tetrahydrofuranyl, Tetrahydrothiofuranyl, 2,3,3a,4,5,6,7,7a-Octahydro-7,8,8-trimethyl-4,7-methanobenzofuran-2-yl); Substituted Ethyl Ethers (1-Ethoxyethyl, 1-(2-Chloroethoxy)ethyl, 1-Methyl-1-methoxyethyl, 1-Methyl-1-benzyloxyethyl, 1-Methyl-1-benzyloxy-2-fluoroethyl, 2,2,2-Trichloroethyl, 2-Trimethylsilylethyl, 2-(Phenylselenyl)ethyl, t-Butyl, Allyl, p-Chlorophenyl, p-Methoxyphenyl, 2,4-Dinitrophenyl, Benzyl); Substituted Benzyl Ethers (p-Methoxybenzyl, 3,4-Dimethoxybenzyl, o-Nitrobenzyl, p-Nitrobenzyl, p-Halobenzyl, 2,6-Dichlorobenzyl, p-Cyanobenzyl, p-Phenylbenzyl, 2- and 4-Picolyl, 3-Methyl-2-picolyl N-Oxido, Diphenylmethyl, p, p'-Dinitrobenzhydryl, 5-Dibenzosuberyl, Triphenylmethyl, alpha-Naphthylidiphenylmethyl, p-methoxyphenyldiphenylmethyl, Di(p-methoxyphenyl)phenylmethyl, Tri(p-methoxyphenyl)methyl, 4-(4'-Bromophenacyloxy)phenyldiphenylmethyl, 4,4', 4"-Tris(4,5-dichlorophthalimidophenyl)methyl, 4,4', 4"-Tris(levulinoyloxyphenyl)methyl, 4,4', 4"-Tris(benzoyloxyphenyl)methyl, 3-(Imidazol-1-ylmethyl)bis(4', 4"-dimethoxyphenyl)methyl, 1,1-Bis(4-methoxyphenyl)-1'-pyrenylmethyl, 9-Anthryl, 9-(9-Phenyl)xanthenyl, 9-(9-Phenyl-10-oxo)anthryl, 1,3-Benzodithiolan-2-yl, Benzisothiazolyl S,S-Dioxido); Silyl Ethers (Trimethylsilyl, Triethylsilyl, Triisopropylsilyl, Dimethylisopropylsilyl, Diethylisopropylsilyl, Dimethylthexylsilyl, t-Butyldimethylsilyl, t-Butyldiphenylsilyl, Tribenzylsilyl, Tri-p-xylylsilyl, Triphenylsilyl, Diphenylmethylsilyl, t-Butylmethoxyphenylsilyl); Esters (Formate, Benzoylformate, Acetate, Choroacetate, Dichloroacetate, Trichloroacetate, Trifluoroacetate, Methoxyacetate, Triphenylmethoxyacetate, Phenoxyacetate, p-Chlorophenoxyacetate, p-poly-Phenylacetate, 3-Phenylpropionate, 4-Oxopentanoate (Levulinate), 4,4-(Ethylenedithio)pentanoate, Pivaloate, Adamantoate, Crotonate, 4-Methoxycrotonate, Benzoate, p-Phenylbenzoate, 2,4,6-

- Trimethylbenzoate (Mesitoate); Carbonates (Methyl, 9-Fluorenylmethyl, Ethyl, 2,2,2-Trichloroethyl, 2-(Trimethylsilyl)ethyl, 2-(Phenylsulfonyl)ethyl, 2-(Triphenylphosphonio)ethyl, Isobutyl, Vinyl, Allyl, p-Nitrophenyl, Benzyl, p-Methoxybenzyl, 3,4-Dimethoxybenzyl, o-Nitrobenzyl, p-Nitrobenzyl, S-Benzyl Thiocarbonate, 4-Ethoxy-1-naphthyl, Methyl
- 5 Dithiocarbonate); Groups With Assisted Cleavage (2-Iodobenzoate, 4-Azidobutyrate, 4-Nitro-4-methylpentanoate, o-(Dibromomethyl)benzoate, 2-Formylbenzenesulfonate, 2-(Methylthiomethoxy)ethyl Carbonate, 4-(Methylthiomethoxy)butyrate, 2-(Methylthiomethoxymethyl)benzoate); Miscellaneous Esters (2,6-Dichloro-4-methylphenoxyacetate, 2,6-Dichloro-4-(1,1,3,3-tetramethylbutyl)phenoxyacetate, 2,4-Bis(1,1-
- 10 dimethylpropyl)phenoxyacetate, Chorodiphenylacetate, Isobutyrate, Monosuccinoate, (E)-2-Methyl-2-butenate (Tigloate), o-(Methoxycarbonyl)benzoate, p-poly-Benzoate,  $\alpha$ -Naphthoate, Nitrate, Alkyl N,N,N', N'-Tetramethylphosphorodiamidate, N-Phenylcarbamate, Borate, Dimethylphosphinothioyl, 2,4-Dinitrophenylsulfenate); and Sulfonates (Sulfate, Methanesulfonate (Mesylate), Benzylsulfonate, Tosylate).
- 15 More typically hydroxy protecting groups include substituted methyl ethers, substituted benzyl ethers, silyl ethers, and esters including sulfonic acid esters, still more typically, trialkylsilyl ethers, tosylates and acetates.
- Typical 1,2- and 1,3-diol protecting groups are described in Greene at pages 118-142 and include Cyclic Acetals and Ketals (Methylene, Ethylidene, 1-t-Butylethylidene, 1-
- 20 Phenylethylidene, (4-Methoxyphenyl)ethylidene, 2,2,2-Trichloroethylidene, Acetonide (Isopropylidene), Cyclopentylidene, Cyclohexylidene, Cycloheptylidene, Benzylidene, p-Methoxybenzylidene, 2,4-Dimethoxybenzylidene, 3,4-Dimethoxybenzylidene, 2-Nitrobenzylidene); Cyclic Ortho Esters (Methoxymethylene, Ethoxymethylene, Dimethoxymethylene, 1-Methoxyethylidene, 1-Ethoxyethylidene, 1,2-Dimethoxyethylidene, alpha-
- 25 Methoxybenzylidene, 1-(N,N-Dimethylamino)ethylidene Derivative, alpha-(N,N-Dimethylamino)benzylidene Derivative, 2-Oxacyclopentylidene); and Silyl Derivatives (Di-t-butylsilylene Group, 1,3-(1,1,3,3-Tetraisopropylidisiloxanylidene) Derivative, Tetra-t-butoxydisiloxane-1,3-diylidene Derivative, Cyclic Carbonates, Cyclic Boronates, Ethyl Boronate, Phenyl Boronate).
- 30 More typically, 1,2- and 1,3-diol protecting groups include epoxides and acetonides.
- Typical amino protecting groups are described in Greene at pages 315-385 and include Carbamates (Methyl and Ethyl, 9-Fluorenylmethyl, 9(2-Sulfo)fluorenylmethyl, 9-(2,7-Dibromo)fluorenylmethyl, 2,7-Di-t-butyl-[9-(10,10-dioxo-10,10,10-tetrahydrothioxanthyl)]-methyl, 4-Methoxyphenacyl); Substituted Ethyl (2,2,2-Trichloroethyl, 2-Trimethylsilylethyl, 2-
- 35 Phenylethyl, 1-(1-Adamantyl)-1-methylethyl, 1,1-Dimethyl-2-haloethyl, 1,1-Dimethyl-2,2-



dibromoethyl, 1,1-Dimethyl-2,2,2-trichloroethyl, 1-Methyl-1-(4-biphenyl)ethyl, 1-(3,5-Di-  
 butylphenyl)-1-methylethyl, 2-(2'- and 4'-Pyridyl)ethyl, 2-(N,N-Dicyclohexylcarboxamido)ethyl, t-  
 Butyl, 1-Adamantyl, Vinyl, Allyl, 1-Isopropylallyl, Cinnamyl, 4-Nitrocinnamyl, 8-Quinolyl, N-  
 Hydroxypiperidinyl, Alkyldithio, Benzyl, p-Methoxybenzyl, p-Nitrobenzyl, p-Bromobenzyl, p-  
 5 Chorobenzyl, 2,4-Dichlorobenzyl, 4-Methylsulfinylbenzyl, 9-Anthrylmethyl, Diphenylmethyl);  
 Groups With Assisted Cleavage (2-Methylthioethyl, 2-Methylsulfonyl, 2-(p-  
 Toluenesulfonyl)ethyl, [2-(1,3-Dithianyl)]methyl, 4-Methylthiophenyl, 2,4-Dimethylthiophenyl, 2-  
 Phosphonioethyl, 2-Triphenylphosphonioisopropyl, 1,1-Dimethyl-2-cyanoethyl, m-Choro-p-  
 acyloxybenzyl, p-(Dihydroxyboryl)benzyl, 5-Benzisoxazolylmethyl, 2-(Trifluoromethyl)-6-  
 10 chromonylmethyl); Groups Capable of Photolytic Cleavage (m-Nitrophenyl, 3,5-  
 Dimethoxybenzyl, o-Nitrobenzyl, 3,4-Dimethoxy-6-nitrobenzyl, Phenyl(o-nitrophenyl)methyl);  
 Urea-Type Derivatives (Phenothiazinyl-(10)-carbonyl Derivative, N'-p-  
 Toluenesulfonylaminocarbonyl, N'-Phenylaminothiocarbonyl); Miscellaneous Carbamates (t-  
 Amyl, S-Benzyl Thiocarbamate, p-Cyanobenzyl, Cyclobutyl, Cyclohexyl, Cyclopentyl,  
 15 Cyclopropylmethyl, p-Decyloxybenzyl, Diisopropylmethyl, 2,2-Dimethoxycarbonylvinyl, o-(N,N-  
 Dimethylcarboxamido)benzyl, 1,1-Dimethyl-3-(N,N-dimethylcarboxamido)propyl, 1,1-  
 Dimethylpropynyl, Di(2-pyridyl)methyl, 2-Furanylmethyl, 2-Iodoethyl, Isobornyl, Isobutyl,  
 Isonicotinyl, p-(p'-Methoxyphenylazo)benzyl, 1-Methylcyclobutyl, 1-Methylcyclohexyl, 1-Methyl-  
 1-cyclopropylmethyl, 1-Methyl-1-(3,5-dimethoxyphenyl)ethyl, 1-Methyl-1-(p-  
 20 phenylazophenyl)ethyl, 1-Methyl-1-phenylethyl, 1-Methyl-1-(4-pyridyl)ethyl, Phenyl, p-  
 (Phenylazo)benzyl, 2,4,6-Tri-t-butylphenyl, 4-(Trimethylammonium)benzyl, 2,4,6-  
 Trimethylbenzyl); Amides (N-Formyl, N-Acetyl, N-Choroacetyl, N-Trichoroacetyl, N-  
 Trifluoroacetyl, N-Phenylacetyl, N-3-Phenylpropionyl, N-Picolinoyl, N-3-Pyridylcarboxamide, N-  
 Benzoylphenylalanyl Derivative, N-Benzoyl, N-p-Phenylbenzoyl); Amides With Assisted  
 25 Cleavage (N-o-Nitrophenylacetyl, N-o-Nitrophenoxycetyl, N-Acetoacetyl, (N'-  
 Dithiobenzoyloxycarbonylamino)acetyl, N-3-(p-Hydroxyphenyl)propionyl, N-3-(o-  
 Nitrophenyl)propionyl, N-2-Methyl-2-(o-nitrophenoxycetyl)propionyl, N-2-Methyl-2-(o-  
 phenylazophenoxy)propionyl, N-4-Chlorobutyryl, N-3-Methyl-3-nitrobutyryl, N-o-  
 Nitrocinnamoyl, N-Acetylmethionine Derivative, N-o-Nitrobenzoyl, N-o-  
 30 (Benzoyloxymethyl)benzoyl, 4,5-Diphenyl-3-oxazolin-2-one); Cyclic Imide Derivatives (N-  
 Phthalimide, N-Dithiasuccinoyl, N-2,3-Diphenylmaleoyl, N-2,5-Dimethylpyrrolyl, N-1,1,4,4-  
 Tetramethyldisilylazacyclopentane Adduct, 5-Substituted 1,3-Dimethyl-1,3,5-triazacyclohexan-2-  
 one, 5-Substituted 1,3-Dibenzyl-1,3,5-triazacyclohexan-2-one, 1-Substituted 3,5-Dinitro-4-  
 pyridonyl); N-Alkyl and N-Aryl Amines (N-Methyl, N-Allyl, N-[2-(Trimethylsilyl)ethoxy]methyl,  
 35 N-3-Acetoxypropyl, N-(1-Isopropyl-4-nitro-2-oxo-3-pyrrolin-3-yl), Quaternary Ammonium Salts,

N-Benzyl, N-Di(4-methoxyphenyl)methyl, N-5-Dibenzosuberyl, N-Triphenylmethyl, N-(4-Methoxyphenyl)diphenylmethyl, N-9-Phenylfluorenyl, N-2,7-Dichloro-9-fluorenylmethylene, N-Ferrocenylmethyl, N-2-Picolylamine N'-Oxide); Imine Derivatives (N-1,1-Dimethylthiomethylene, N-Benzylidene, N-p-methoxybenzylidene, N-Diphenylmethylene, N-(2-Pyridyl)mesityl)methylene, N, (N', N'-Dimethylaminomethylene, N, N'-Isopropylidene, N-p-Nitrobenzylidene, N-Salicylidene, N-5-Chlorosalicylidene, N-(5-Chloro-2-hydroxyphenyl)phenylmethylene, N-Cyclohexylidene); Enamine Derivative (N-(5,5-Dimethyl-3-oxo-1-cyclohexenyl)); N-Metal Derivatives (N-Borane Derivatives, N-Diphenylborinic Acid Derivative, N-[Phenyl(pentacarbonylchromium- or -tungsten)]carbenyl, N-Copper or N-Zinc Chelate); N-N Derivatives (N-Nitro, N-Nitroso, N-Oxide); N-P Derivatives (N-Diphenylphosphinyl, N-Dimethylthiophosphinyl, N-Diphenylthiophosphinyl, N-Dialkyl Phosphoryl, N-Dibenzyl Phosphoryl, N-Diphenyl Phosphoryl); N-Si Derivatives; N-S Derivatives; N-Sulfenyl Derivatives (N-Benzenesulfenyl, N-o-Nitrobenzenesulfenyl, N-2,4-Dinitrobenzenesulfenyl, N-Pentachlorobenzenesulfenyl, N-2-nitro-4-methoxybenzenesulfenyl, N-Triphenylmethylsulfenyl, N-3-Nitropyridinesulfenyl); and N-Sulfonyl Derivatives (N-p-Toluenesulfonyl, N-Benzenesulfonyl, N-2,3,6-Trimethyl-4-methoxybenzenesulfonyl, N-2,4,6-Trimethoxybenzenesulfonyl, N-2,6-Dimethyl-4-methoxybenzenesulfonyl, N-Pentamethylbenzenesulfonyl, N-2,3,5,6-Tetramethyl-4-methoxybenzenesulfonyl, N-4-methoxybenzenesulfonyl, N-2,4,6-Trimethylbenzenesulfonyl, N-2,6-Dimethoxy-4-methylbenzenesulfonyl, N-2,2,5,7,8-Pentamethylchroman-6-sulfonyl, N-Methanesulfonyl, N-beta.-Trimethylsilyethanesulfonyl, N-9-Anthracenesulfonyl, N-4-(4', 8'-Dimethoxynaphthylmethyl)benzenesulfonyl, N-Benzylsulfonyl, N-Trifluoromethylsulfonyl, N-Phenacysulfonyl).

More typically, amino protecting groups include carbamates and amides, still more typically, N-acetyl groups.

**Stereoisomers.** The formula 1 compounds include enriched or resolved optical isomers at any or all asymmetric atoms as are apparent from the depictions. Both racemic and diastereomeric mixtures, as well as the individual optical isomers can be isolated or synthesized so as to be substantially free of their enantiomeric or diastereomeric partners, and these are all within the scope of the invention. Chiral centers may be found in invention compounds at, for example, R<sup>1</sup>, R<sup>2</sup> or R<sup>4</sup>.

One or more of the following methods are used to prepare the enantiomerically enriched or pure isomers herein. The methods are listed in approximately their order of preference, i.e.; one ordinarily should employ stereospecific synthesis from chiral precursors before chromatographic resolution before spontaneous crystallization.

Stereospecific synthesis is described in the examples. Methods of this type conveniently are used when the appropriate chiral starting material is available and reaction steps are chosen that do not result in undesired racemization at chiral sites. One advantage of stereospecific synthesis is that it does not produce undesired enantiomers that must be removed from the final product, thereby lowering overall synthetic yield. In general, those skilled in the art would understand what starting materials and reaction conditions should be used to obtain the desired enantiomerically enriched or pure isomers by stereospecific synthesis.

If a suitable stereospecific synthesis cannot be empirically designed or determined with routine experimentation then those skilled in the art would turn to other methods. One method of general utility is chromatographic resolution of enantiomers on chiral chromatography resins. These resins are packed in columns, commonly called Pirkle columns, and are commercially available. The columns contain a chiral stationary phase. The racemate is placed in solution and loaded onto the column, and thereafter separated by HPLC. See for example, Proceedings Chromatographic Society - International Symposium on Chiral Separations, Sept. 3-4, 1987, which is incorporated herein by reference. Examples of chiral columns that could be used to screen for the optimal separation technique would include Diacel Chriacel OD, Regis Pirkle Covalent D-phenylglycine, Regis Pirkle Type 1A, Astec Cyclobond II, Astec Cyclobond III, Serva Chiral D-DL=Daltosil 100, Bakerbond DNBLau, Sumipax OA-1000, Merck Cellulose Triacetate column, Astec Cyclobond I-Beta, or Regis Pirkle Covalent D-Naphthylalanine. Not all of these columns are likely to be effective with every racemic mixture. However, those skilled in the art understand that a certain amount of routine screening may be required to identify the most effective stationary phase. When using such columns it is desirable to employ embodiments of the compounds of this invention in which the charges are not neutralized, e.g., where acidic functionalities such as carboxyl are not esterified or amidated.

Another method entails converting the enantiomers in the mixture to diastereomers with chiral auxiliaries and then separating the conjugates by ordinary column chromatography. This is a very suitable method, particularly when the embodiment contains a free hydroxyl that will form a salt or covalent bond to a chiral auxiliary. Chirally pure amino acids, organic acids or organosulfonic acids are all worthwhile exploring as chiral auxiliaries, all of which are well known in the art. Salts with such auxiliaries can be formed, or they can be covalently (but reversibly) bonded to the functional group.

Enzymatic resolution is another method of potential value. In such methods one prepares covalent derivatives of the enantiomers in the racemic mixture, generally lower alkyl esters, and then exposes the derivative to enzymatic cleavage, generally hydrolysis. For this method to be successful an enzyme must be chosen that is capable of stereospecific cleavage, so it is frequently

necessary to routinely screen several enzymes. If esters are to be cleaved, then one selects a group of esterases, phosphatases, and lipases and determines their activity on the derivative. Typical esterases are from liver, pancreas or other animal organs, and include porcine liver esterase.

If the enantiomeric mixture separates from solution or a melt as a conglomerate, i.e., a mixture of enantiomerically pure crystals, then the crystals can be mechanically separated, thereby producing the enantiomerically enriched preparation. This method, however, is not practical for large-scale preparations and is of limited value for true racemic compounds.

Asymmetric synthesis is another technique for achieving enantiomeric enrichment. For example, a chiral protecting group is reacted with the group to be protected and the reaction mixture allowed to equilibrate. If the reaction is enantiomerically specific then the product will be enriched in that enantiomer.

Further guidance in the separation of enantiomeric mixtures can be found, by way of example and not limitation, in "Enantiomers, Racemates, and resolutions", Jean Jacques, Andre Collet, and Samuel H. Wilen (Krieger Publishing Company, Malabar, FL, 1991, ISBN 0-89464-618-4): Part 2, Resolution of Enantiomer Mixture, pages 217-435; more particularly, section 4, Resolution by Direct Crystallization, pages 217-251, section 5, Formation and Separation of Diastereomers, pages 251-369, section 6, Crystallization-Induced Asymmetric Transformations, pages 369-378, and section 7, Experimental Aspects and Art of Resolutions, pages 378-435; still more particularly, section 5.1.4, Resolution of Alcohols, Transformation of Alcohols into Salt-Forming Derivatives, pages 263-266, section 5.2.3, Covalent Derivatives of Alcohols, Thiols, and Phenols, pages 332-335, section 5.1.1, Resolution of Acids, pages 257-259, section 5.1.2, Resolution of Bases, pages 259-260, section 5.1.3, Resolution of Amino Acids, page 261-263, section 5.2.1, Covalent Derivatives of Acids, page 329, section 5.2.2, Covalent derivatives of Amines, pages 330-331, section 5.2.4, Covalent Derivatives of Aldehydes, Ketones, and Sulfoxides, pages 335-339, and section 5.2.7, Chromatographic Behavior of Covalent Diastereomers, pages 348-354, all of which are incorporated herein by reference.

Embodiments include compositions that transiently occur when a method step or operation is performed. For example, when a formula 1 compound is contacted with an excipient, e.g., water, a cyclodextrin, a PEG, an alcohol, propylene glycol, benzyl alcohol or benzyl benzoate, the composition before addition of one ingredient with another is a non-homogenous mixture. As the ingredients are contacted, the mixture's homogeneity increases and the proportion of ingredients relative to each other approaches a desired value. Thus, some compositions as disclosed herein, optionally contain less than about 3% w/w water, e.g., less than 0.5% w/w water, can comprise about 0.0001-99% w/w of a formula 1 compound such as 16 $\alpha$ -bromoepiandrosterone and one or more excipients. These transient compositions are intermediates that necessarily arise when one

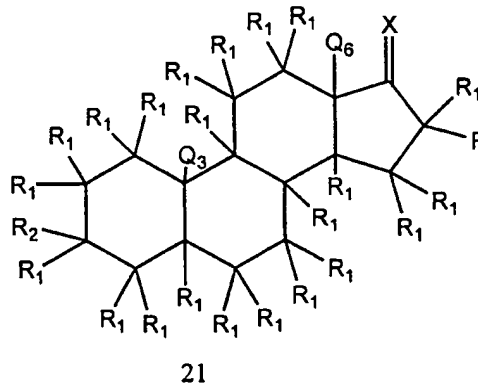
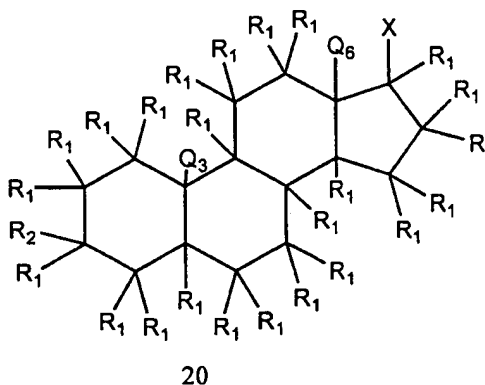
makes an invention composition or formulation and they are included in invention embodiments to the extent that they are patentable.

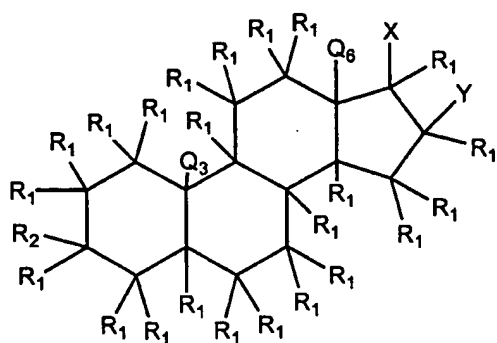
**Formula 1 compounds.** The formula 1 compounds, or the "compounds of the invention", are useful to treat a subject having, or prevent infection of a subject with, one or more

- 5 *Toxoplasmosis* or *Cryptosporidium* parasites. The present invention provides a new method for treating toxoplasmosis and/or cryptosporidiosis by administering compounds of the present invention, as discussed above, including compounds of formula 1 and pharmaceutically acceptable salts thereof.

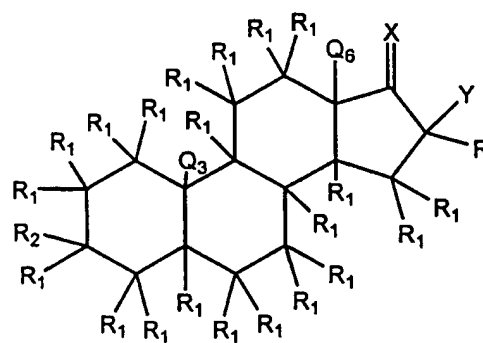
- 10 For preferred formula 1 compounds, the R<sub>2</sub> moiety bonded to the steroid ring is generally in the β-configuration, two R<sub>1</sub> are bonded to Q<sub>2</sub> and X is a double bonded oxygen moiety (=O). Typically, one of the R<sub>1</sub> bonded to Q<sub>2</sub> is hydrogen in the β-configuration, the other R<sub>1</sub> bonded to Q<sub>2</sub> is hydrogen or a halogen, usually bromine, in the α-configuration and a double bond is present at the 5-6 positions. Such preferred compounds include dehydroepiandrosterone ("DHEA") and 16α-bromodehydro-epiandrosterone ("Br-DHEA").

- 15 Other preferred formula 1 compounds include 17-ketosteroids of formula 1 where a double bond is present at the 5-6 positions, X is =O, Q<sub>2</sub> is -CH<sub>2</sub>- or -CHBr-, R<sub>2</sub> is -H, or -OR<sub>3</sub> wherein R<sub>3</sub> is -S(O)(O)-OH, -S(O)(O)-ONa, -S(O)(O)-O-CH<sub>2</sub>-CH(O-C(O)-R<sub>6</sub>)-CH<sub>2</sub>-O-C(O)-R<sub>6</sub> (where R<sub>6</sub> independently is C<sub>1-14</sub> straight or branched alkyl), -P(O)(O)-O-CH<sub>2</sub>-CH(O-C(O)-R<sub>7</sub>)-CH<sub>2</sub>-O-C(O)-R<sub>7</sub> (where R<sub>7</sub> independently is a glucuronide group or C<sub>1-14</sub> straight or branched alkyl) or R<sub>2</sub> is a glucuronide group. Other preferred compounds include compounds  
20 having the formulas 20-43

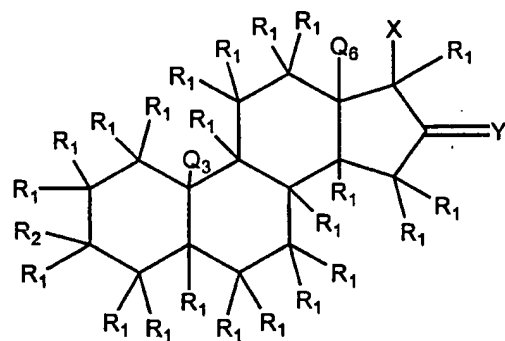




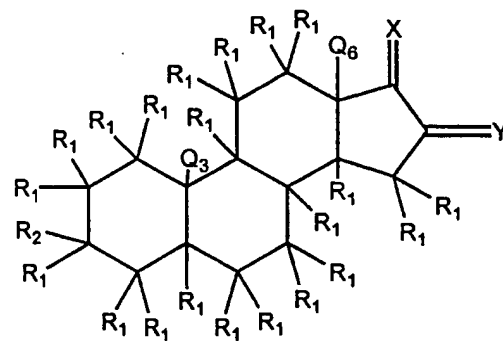
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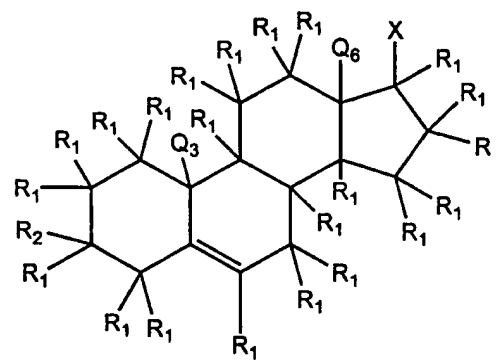
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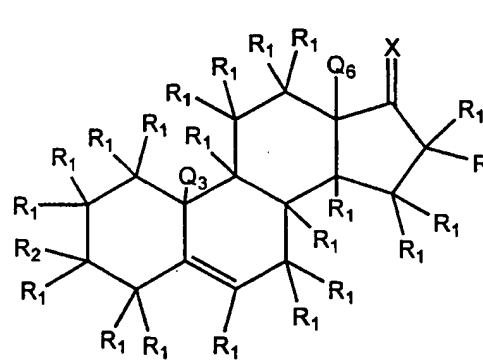
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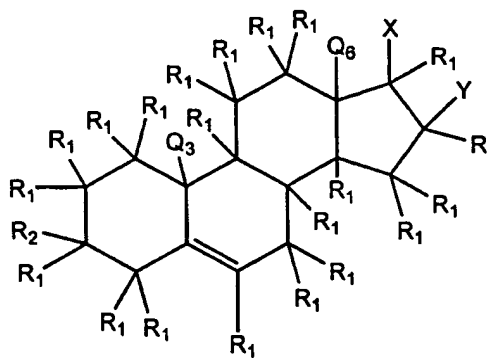


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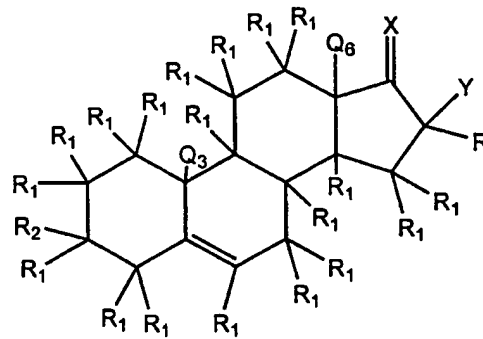


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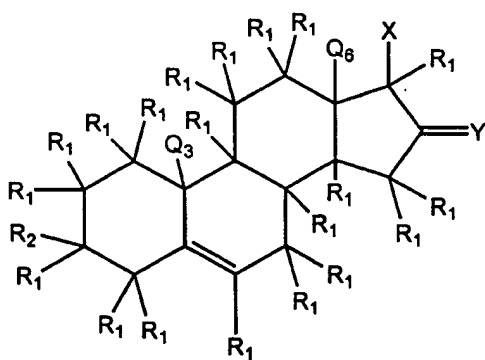
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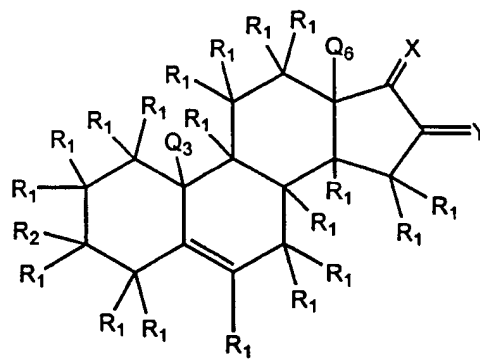
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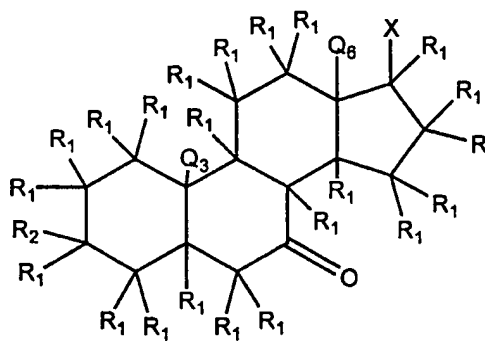
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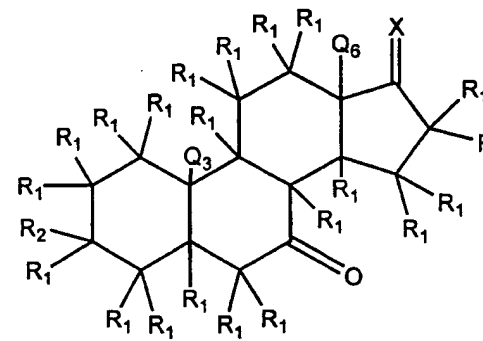
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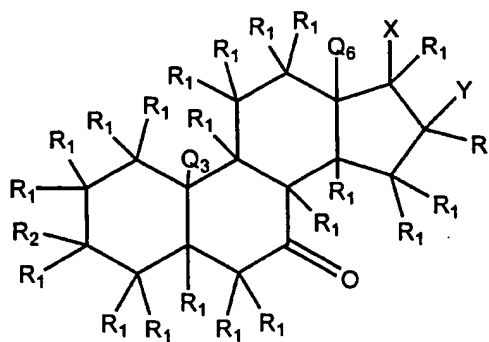


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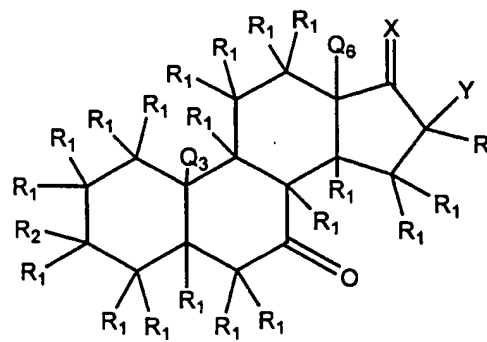


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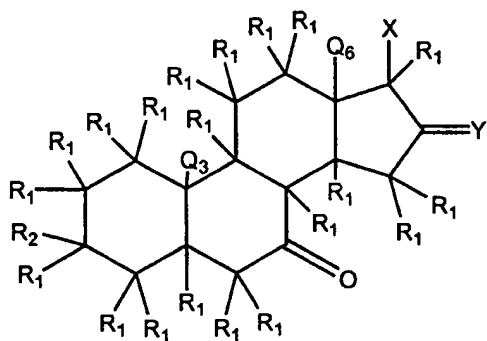
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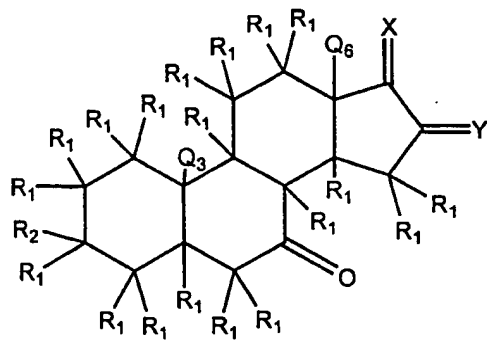
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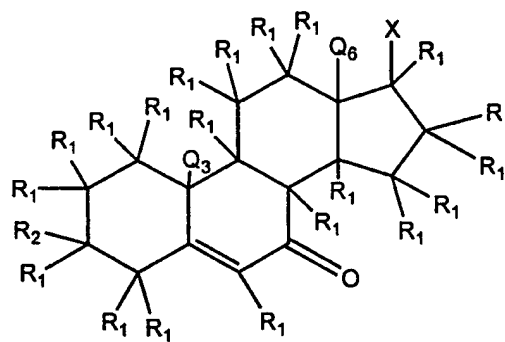
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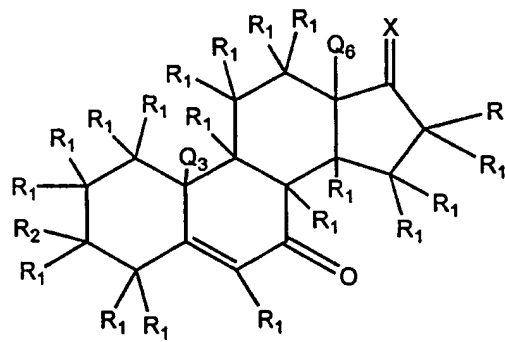
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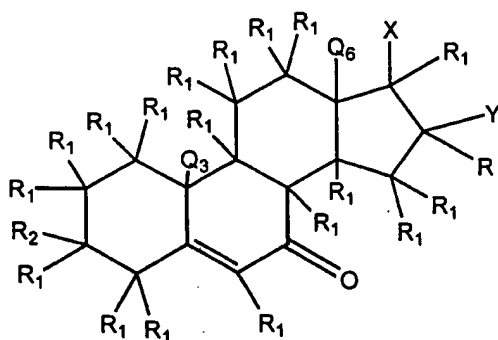
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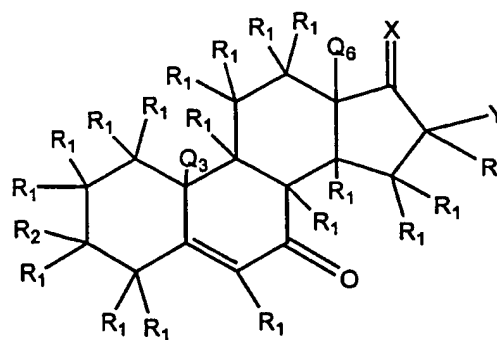
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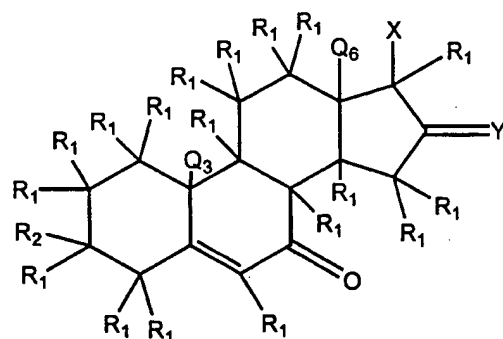




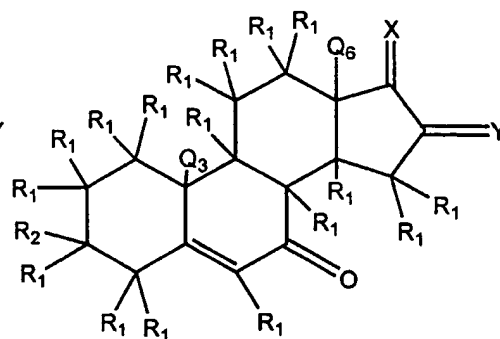
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wherein for each of structures 20-43

Q<sub>3</sub> and Q<sub>6</sub> are each -C(R<sub>1</sub>)<sub>3</sub> wherein each R<sub>1</sub> is independently selected;

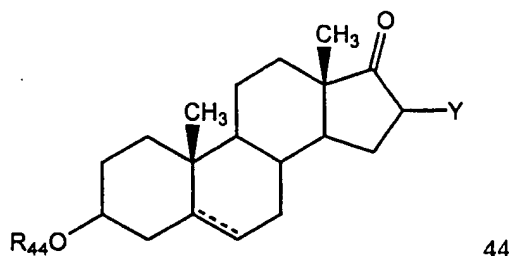
X and Y independently are -OH, -H, lower alkyl (e.g., C<sub>1-6</sub> alkyl), -C(O)-O-R<sub>5</sub>, -O-C(O)-R<sub>5</sub>, halogen or, X and Y together with the R<sub>1</sub> at the same position independently are a ketone (=O);

each R<sub>1</sub> is independently selected and has the definition given above; and

R<sub>2</sub> and R<sub>5</sub> have the definitions given above.

In some embodiments, the formula 1 compound has the structure 20-43 and 2, 3, 4, 5 or 6 R<sub>1</sub> groups independently are -OH, halogen or alkoxy, and the remaining R<sub>1</sub> are all hydrogen; R<sub>2</sub> is -OH, an ester, a thioester or a carbamate, or R<sub>2</sub>, together with the R<sub>1</sub> at the 3-position comprises =O; Y is -H, -OH, a halogen or -O-C(O)-R<sub>5</sub>, or Y, together with the R<sub>1</sub> at the 16-position comprises =O; X is -OH or -O-C(O)-R<sub>5</sub>, or X, together with the R<sub>1</sub> at the 17-position comprises =O; and Q<sub>3</sub> and Q<sub>6</sub> independently are -CH<sub>3</sub> or -CH<sub>2</sub>OH. Such embodiments include structure 20-43 compounds where two -OH are present at the 3-position, the 16-position or at the 17-position.

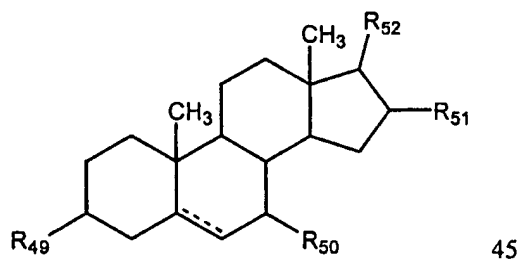
Preferred invention embodiments include compounds having the formula 44



wherein Y is hydrogen or bromine, R<sub>44</sub> is -H, -S(O)(O)-OH, -S(O)(O)-ONa, -S(O)(O)-O-CH<sub>2</sub>-CH(O-C(O)-R<sub>6</sub>)-CH<sub>2</sub>-O-C(O)-R<sub>6</sub>, -P(O)(O)-O-CH<sub>2</sub>-CH(O-C(O)-R<sub>7</sub>)-CH<sub>2</sub>-O-C(O)-R<sub>7</sub> or a glucuronide group of structure (A). In other preferred embodiments, Y and R<sub>44</sub> in formula 44 are both hydrogen. An especially preferred compound is dehydroepiandrosterone (Y and R<sub>44</sub> in formula 44 are both hydrogen and the double bond at the 5-6 position is present). In other embodiments, the compound is epiandrosterone (Y and R<sub>44</sub> in formula 44 are both hydrogen and the double bond at the 5-6 position is absent). A 16-haloepiandrosterone with a F, Cl, Br or I at the 16 position can also be used as an antiviral agent, e.g., 16 $\alpha$ -bromoepiandrosterone. Other preferred compounds are (i) 16 $\alpha$ -bromodehydroepiandrosterone, (ii) dehydroepiandrosterone-3-sulfate (Y is -H and R<sub>44</sub> is -S(O)(O)-OM in formula 44 are both hydrogen and the double bond at the 5-6 position is present) and (iii) 5 $\beta$ -androstane-3 $\beta$ -ol-17-one. Related embodiments comprise compounds related to formula 44 compounds comprise the formula 44 compounds wherein 1, 2, 3, 4, 5 or 6 hydrogen atoms that are bonded to the steroid nucleus are substituted with independently selected -OH, -Br, -Cl, -F, -I, -OCH<sub>3</sub> or -OC<sub>2</sub>H<sub>5</sub> atoms or groups.

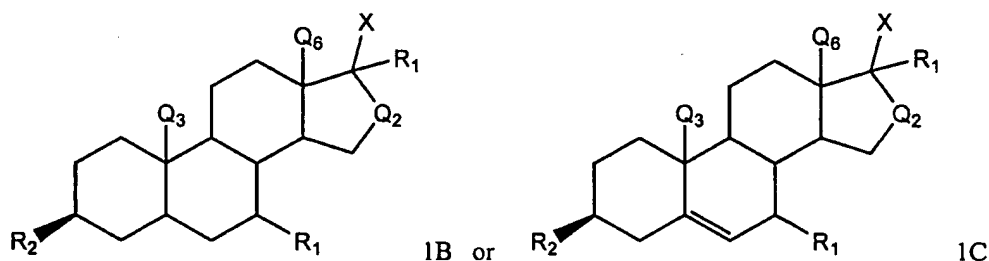
In other embodiments, the 17-ketosteroids of formula 1 are dehydroepiandrosterone where R<sub>44</sub> in formula 44 is a -S(O)(O)-O-CH<sub>2</sub>-CH(O-C(O)-R<sub>6</sub>)-CH<sub>2</sub>-O-C(O)-R<sub>5</sub>, -P(O)(O)-O-CH<sub>2</sub>-CH(O-C(O)-R<sub>7</sub>)-CH<sub>2</sub>-O-C(O)-R<sub>7</sub> or a glucuronide group of structure (A), Y is hydrogen and the 5-6 double bond is present. Other formula 44 compounds include conjugates of dehydroepiandrosterone wherein Y is hydrogen, a double bond is present at the 5-6 position and R<sub>44</sub> is hexyl sulfate, dodecyl sulfate, octadecyl sulfate, octadecanoyl sulfate, O-dihexadecylglycerol sulfate, hexadecane sulfonate, dioctadecanoylglycerol phosphate or O-hexadecylglycerol phosphate.

In another preferred aspect of the invention, the steroid of formula 1 is a compound of formula 45



- wherein  $R_{50}$  is -H, -OH or =O;  $R_{51}$  is -Br, -Cl, -F or -I;  $R_{52}$  is -OH or =O;  $R_{49}$  is -H, -OH, or -OR<sub>53</sub>; and  $R_{53}$  is C<sub>1-18</sub> alkyl, C<sub>2-18</sub> alkenyl, C<sub>2-18</sub> alkynyl, a C<sub>1-18</sub> ester, a C<sub>1-18</sub> thioester, wherein any of the foregoing C<sub>1-18</sub> or C<sub>2-18</sub> groups is substituted at one or more hydrogen atoms with one or more independently selected -O-, -S-, -OH, -NH<sub>2</sub> or -SH groups or  $R_{53}$  is a thioacetal, a sulfate ester, a sulfonate ester, a carbamate or a thioester. In one preferred aspect,  $R_{49}$  is -O-C(O)-CH<sub>2</sub>-CH<sub>2</sub>-CH( $R_{54}$ )-CH( $R_{55}$ )-CH<sub>2</sub> $R_{56}$  wherein  $R_{54}$  is -NH<sub>2</sub>, -OH, -SH, -O-PO<sub>3</sub>, -SO<sub>3</sub> or -OSO<sub>3</sub>;  $R_{55}$  is -H, -NH<sub>2</sub>, -OH, -SH, -O-PO<sub>3</sub>, -SO<sub>3</sub> or -OSO<sub>3</sub>; and  $R_{56}$  is C<sub>1-18</sub> alkyl, C<sub>2-18</sub> alkenyl, C<sub>2-18</sub> alkynyl, a C<sub>1-18</sub> ester, a C<sub>1-18</sub> thioester, wherein any of the foregoing C<sub>1-18</sub> or C<sub>2-18</sub> groups is substituted at one or more hydrogen atoms with one or more independently selected -OH, -NH<sub>2</sub>, -SH or =O groups, and the precursors, metabolites and analogs thereof.
- Related embodiments comprise compounds related to formula 44 compounds comprise the formula 45 compounds wherein 1, 2, 3, 4, 5 or 6 hydrogen atoms that are bonded to the steroid nucleus are substituted with independently selected -OH, -Br, -Cl, -F, -I, -OCH<sub>3</sub> or -OC<sub>2</sub>H<sub>5</sub> atoms or groups.

In other preferred embodiments, the formula 1 compounds have the formula 1B or 1C



- wherein each  $R_1$  independently is -H, -OH, a halogen, -CHCH<sub>2</sub>, -CHCHCH<sub>3</sub>, -CCH, -CCCH<sub>3</sub>, or, or, the other moiety that is bonded to the same carbon atom is absent and  $R_1$  is =O;  $R_2$  is -H, -OH, a halogen, C<sub>1-8</sub> alkoxy, -S-C(O)-(CH<sub>2</sub>)<sub>m</sub>- $R_4$ , -C(O)-S-(CH<sub>2</sub>)<sub>m</sub>- $R_4$ , -O-S(O)(O)-(CH<sub>2</sub>)<sub>m</sub>- $R_4$ , -O-S(O)(O)-O-(CH<sub>2</sub>)<sub>m</sub>- $R_4$ , -O-C(O)-NH-(CH<sub>2</sub>)<sub>m</sub>- $R_4$ , -NH-C(O)-O-(CH<sub>2</sub>)<sub>m</sub>- $R_4$ , -O-C(S)-(CH<sub>2</sub>)<sub>m</sub>- $R_4$ , -C(S)-O-(CH<sub>2</sub>)<sub>m</sub>- $R_4$ , -O-C(O)-(CH<sub>2</sub>)<sub>m</sub>- $R_4$  or -C(O)-O-(CH<sub>2</sub>)<sub>m</sub>- $R_4$ ;  $R_4$  is -H, -CH<sub>3</sub>, -C<sub>2</sub>H<sub>5</sub>, -C<sub>3</sub>H<sub>7</sub>, -C<sub>2</sub>H<sub>4</sub>OH, -C<sub>3</sub>H<sub>6</sub>OH, -CH<sub>2</sub>-CH<sub>2</sub>-O-CH<sub>3</sub>, -CH<sub>2</sub>-CH<sub>2</sub>-O-CH<sub>2</sub>-CH<sub>3</sub>, -CH<sub>2</sub>-CH<sub>2</sub>-O-CH<sub>2</sub>-CH<sub>2</sub>OH, a C<sub>3-6</sub> alkenyl group, a C<sub>3-6</sub> alkynyl group, benzyl or phenyl, wherein the phenyl or benzyl groups are optionally substituted with 1, 2, or 3 independently selected halogen, C<sub>1-4</sub>

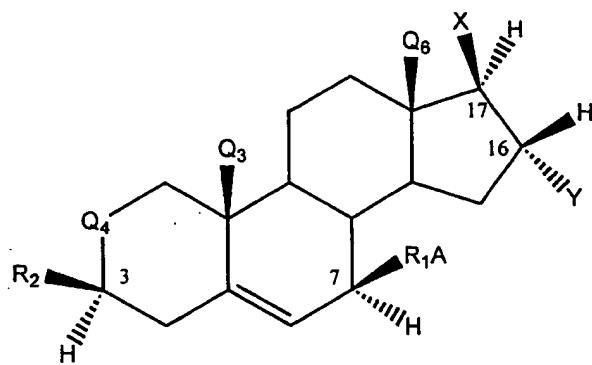
alkoxy, -OH, -SH, -O- or -NH- moieties; and Q<sub>3</sub> and Q<sub>6</sub> independently are -H, -CH<sub>3</sub> or -CH<sub>2</sub>OH; and Q<sub>2</sub> is -C(R<sub>1</sub>)<sub>2</sub>- or -CH<sub>2</sub>-CH<sub>2</sub>-. In these embodiments, Q<sub>3</sub> and Q<sub>6</sub> are usually both in the β-configuration, typically they are -CH<sub>3</sub>, Q<sub>2</sub> usually comprises -CH<sub>2</sub>-, -C(O)-, -CH(Br)-, -CH(I)-, or -CH(OH)- with the Br, I or OH moieties in the α-configuration, or Q<sub>2</sub> comprises =O, and R<sub>1</sub> at the 7-position is -H, -OH or =O. Related embodiments comprise compounds related to formula 44 compounds comprise the formula 1A or 1B compounds wherein 1, 2, 3, 4, 5 or 6 hydrogen atoms that are bonded to the steroid nucleus are substituted with independently selected -OH, -Br, -Cl, -F, -I, -OCH<sub>3</sub> or -OC<sub>2</sub>H<sub>5</sub> atoms or groups.

The formula 1 compounds can exist in a crystalline or polymorphic form.

**Metabolites.** Also falling within the scope of this invention are the *in vivo* metabolites of the compounds of the invention, to the extent such products are novel and unobvious over the prior art. Such products may result for example from the oxidation, reduction, hydrolysis, amidation, esterification and the like of the administered formula 1 compound, due to enzymatic or chemical processes. Accordingly, the invention includes novel and unobvious compounds produced by a process comprising contacting a compound of this invention with a subject, e.g., a human, rodent or a primate, for a period of time sufficient to yield a metabolic product thereof. Such products typically are identified by preparing a radiolabelled (e.g. C<sup>14</sup> or H<sup>3</sup>) formula 1 compound, administering it parenterally or orally in a detectable dose (e.g. greater than about 0.5 mg/kg) to an animal such as rat, mouse, guinea pig, primate, or to a human, allowing sufficient time for metabolism to occur (typically about 30 seconds to about 30 hours) and isolating its conversion products from the urine, blood or other biological samples. These products are easily isolated since they are labeled (others are isolated by the use of antibodies capable of binding epitopes surviving in the metabolite). The metabolite structures are determined in conventional fashion, e.g. by HPLC, MS or NMR analysis. In general, analysis of metabolites is done in the same way as conventional drug metabolism studies well-known to those skilled in the art. The conversion products, so long as they are not otherwise found *in vivo*, are useful in diagnostic assays for therapeutic dosing of the compounds of the invention even if they possess no therapeutic activity of their own.

The following description exemplifies embodiments of the formula 1 compounds.

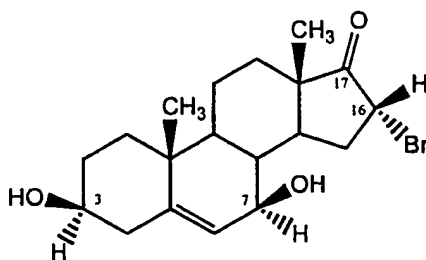
**Group 1.** Exemplary embodiments include the formula 1 compounds named in table B based on the compound structure designations defined in table A. Each compound named in Table B is depicted as a compound of formula 4



4

where Q<sub>3</sub> and Q<sub>6</sub> are both -CH<sub>3</sub>, Q<sub>4</sub> is -CH<sub>2</sub>- and R<sub>2</sub>, R<sub>1A</sub>, and Y and X have the structures designated in Table A. The compounds named according to Tables A and B are referred to as "group 1" compounds.

- 5 Compounds named in Table B are designated by numbers assigned to R<sub>2</sub>, R<sub>1A</sub>, Y and X according to the following compound naming convention, R<sub>2</sub>.R<sub>1A</sub>.Y.X, using the numbered chemical structures depicted in Table A. As shown in formula 4, R<sub>2</sub> is in the 3 $\beta$ -position and hydrogen fills the remaining valence or R<sub>2</sub> is double bonded to the 3 carbon, R<sub>1A</sub> is an R<sub>1</sub> group at the 7 $\beta$ -position or R<sub>1A</sub> is an R<sub>1</sub> group double bonded to the 7 carbon, Y is in the 16 $\alpha$ -position and hydrogen fills the remaining valence or R<sub>2</sub> is double bonded to the 16 carbon and X is in the 17 $\beta$ -position and hydrogen fills the remaining valence or X is double bonded to the 17 carbon. When R<sub>2</sub>, R<sub>1A</sub>, Y or X is a divalent moiety, e.g., =O, the hydrogen at the corresponding position is absent. Thus, the group 1 compound named 1.2.1.1 specifies a formula 4 structure with a  $\beta$ -hydroxyl bonded to carbons at the 3- and 7-positions (the variable groups R<sub>2</sub> and R<sub>1A</sub> respectively), an  $\alpha$ -bromine bonded to carbon 16 (the variable group Y) and double bonded oxygen (=O) at carbon 17 (the variable group X), i.e., having the structure shown below.



1.2.1.1

TABLE A

20	R <sub>2</sub>	R <sub>1A</sub>
	1 -OH	1 -H
	2 =O	2 -OH
	3 -O-P(O)(O)-OH	3 =O

	4 -O-P(O)(O)-O-CH <sub>2</sub> -CH(O-C(O)-CH <sub>3</sub> )-CH <sub>2</sub> -O-C(O)CH <sub>3</sub>	4 -CH <sub>3</sub>
	5 -O-S(O)(O)-OH	5 -OCH <sub>3</sub>
	6 -O-S(O)(O)-O-Na <sup>+</sup>	6 -OC <sub>2</sub> H <sub>5</sub>
	7 -O-S(O)(O)-OC <sub>2</sub> H <sub>5</sub>	7 -OCH <sub>2</sub> CH <sub>2</sub> CH <sub>3</sub>
5	8 -O-S(O)(O)-O-CH <sub>2</sub> -CH(O-C(O)-CH <sub>3</sub> )-CH <sub>2</sub> -O-C(O)CH <sub>3</sub>	8 -OCH(CH <sub>3</sub> )CH <sub>3</sub>
	9 -O-S(O)(O)-OCH <sub>2</sub> CH <sub>2</sub> CH <sub>2</sub> CH <sub>3</sub>	9 -OCH <sub>2</sub> CH <sub>2</sub> CH <sub>2</sub> CH <sub>3</sub>
	10 -O-S(O)(O)-OC(CH <sub>3</sub> ) <sub>3</sub>	10 -OC(CH <sub>3</sub> ) <sub>3</sub>

	Y	X
10	1 -Br	1 =O
	2 -Cl	2 -OH
	3 -I	3 -H
	4 -F	4 -F
	5 -H	5 -Cl
15	6 -OH	6 -Br
	7 =O	7 -I
	8 -O-C(O)-CH <sub>3</sub>	8 -O-C(O)-CH <sub>3</sub>
	9 -O-C(O)-CH <sub>2</sub> CH <sub>3</sub>	9 -O-C(O)-CH <sub>2</sub> CH <sub>3</sub>
	10 -O-C(O)-CH <sub>2</sub> CH <sub>2</sub> CH <sub>3</sub>	10 -O-C(O)-CH <sub>2</sub> CH <sub>2</sub> CH <sub>3</sub>

20

TABLE B

	1.1.1.1, 1.1.1.2, 1.1.1.3, 1.1.1.4, 1.1.1.5, 1.1.1.6, 1.1.1.7, 1.1.1.8, 1.1.1.9, 1.1.1.10, 1.1.2.1, 1.1.2.2,
	1.1.2.3, 1.1.2.4, 1.1.2.5, 1.1.2.6, 1.1.2.7, 1.1.2.8, 1.1.2.9, 1.1.2.10, 1.1.3.1, 1.1.3.2, 1.1.3.3, 1.1.3.4,
	1.1.3.5, 1.1.3.6, 1.1.3.7, 1.1.3.8, 1.1.3.9, 1.1.3.10, 1.1.4.1, 1.1.4.2, 1.1.4.3, 1.1.4.4, 1.1.4.5, 1.1.4.6,
25	1.1.4.7, 1.1.4.8, 1.1.4.9, 1.1.4.10, 1.1.5.1, 1.1.5.2, 1.1.5.3, 1.1.5.4, 1.1.5.5, 1.1.5.6, 1.1.5.7, 1.1.5.8,
	1.1.5.9, 1.1.5.10, 1.1.6.1, 1.1.6.2, 1.1.6.3, 1.1.6.4, 1.1.6.5, 1.1.6.6, 1.1.6.7, 1.1.6.8, 1.1.6.9, 1.1.6.10,
	1.1.7.1, 1.1.7.2, 1.1.7.3, 1.1.7.4, 1.1.7.5, 1.1.7.6, 1.1.7.7, 1.1.7.8, 1.1.7.9, 1.1.7.10, 1.1.8.1, 1.1.8.2,
	1.1.8.3, 1.1.8.4, 1.1.8.5, 1.1.8.6, 1.1.8.7, 1.1.8.8, 1.1.8.9, 1.1.8.10, 1.1.9.1, 1.1.9.2, 1.1.9.3, 1.1.9.4,
	1.1.9.5, 1.1.9.6, 1.1.9.7, 1.1.9.8, 1.1.9.9, 1.1.9.10, 1.1.10.1, 1.1.10.2, 1.1.10.3, 1.1.10.4, 1.1.10.5,
30	1.1.10.6, 1.1.10.7, 1.1.10.8, 1.1.10.9, 1.1.10.10, 1.2.1.1, 1.2.1.2, 1.2.1.3, 1.2.1.4, 1.2.1.5, 1.2.1.6,
	1.2.1.7, 1.2.1.8, 1.2.1.9, 1.2.1.10, 1.2.2.1, 1.2.2.2, 1.2.2.3, 1.2.2.4, 1.2.2.5, 1.2.2.6, 1.2.2.7, 1.2.2.8,
	1.2.2.9, 1.2.2.10, 1.2.3.1, 1.2.3.2, 1.2.3.3, 1.2.3.4, 1.2.3.5, 1.2.3.6, 1.2.3.7, 1.2.3.8, 1.2.3.9, 1.2.3.10,
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1.3.5.9, 1.3.5.10, 1.3.6.1, 1.3.6.2, 1.3.6.3, 1.3.6.4, 1.3.6.5, 1.3.6.6, 1.3.6.7, 1.3.6.8, 1.3.6.9, 1.3.6.10,  
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1.4.2.9, 1.4.2.10, 1.4.3.1, 1.4.3.2, 1.4.3.3, 1.4.3.4, 1.4.3.5, 1.4.3.6, 1.4.3.7, 1.4.3.8, 1.4.3.9, 1.4.3.10,  
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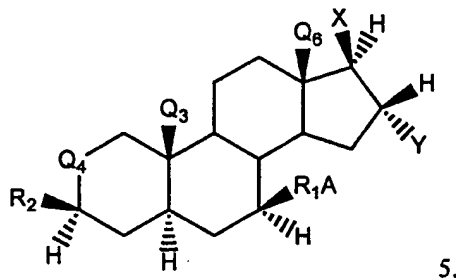
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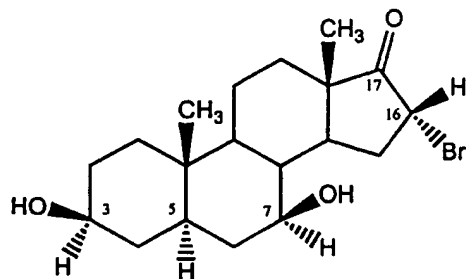
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Additional exemplary formula 1 compound groups include the following groups as disclosed below.

**Group 2.** Group 2 compounds are as named in Table B, i.e.,  $R_2$ ,  $R_{1A}$ , Y and X substituents are as defined in Table A, but they are bonded to the steroid nucleus shown in formula 5, which is the same as the formula 4 steroid nucleus, except that the 5-6 double bond is absent and hydrogen is present at the 5-position in the  $\alpha$ -configuration



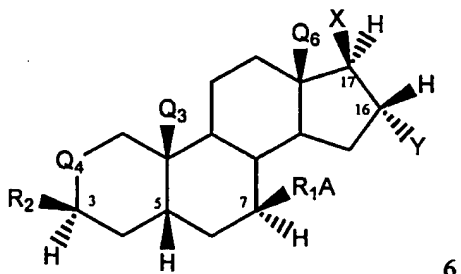
Thus, the group 2 compound named 1.2.1.1 has the structure



group 2, compound 1.2.1.1.

10

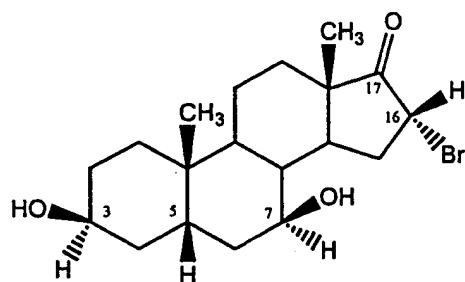
**Group 3.** Group 3 compounds are as named in Table B, i.e.,  $R_2$ ,  $R_{1A}$ , Y and X substituents are as defined in Table A, but they are bonded to the steroid nucleus shown in formula 6, which is the same as the formula 4 steroid nucleus, except that the 5-6 double bond is absent and hydrogen is present at the 5-position in the  $\beta$ -configuration



15

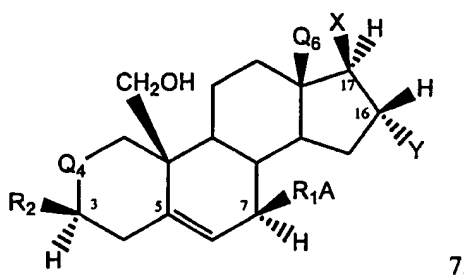
Thus, the group 3 compound named 1.2.1.1 has the structure





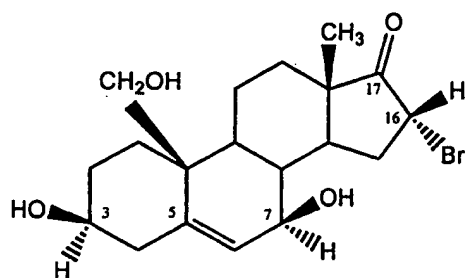
group 3, compound 1.2.1.1.

**Group 4.** Group 4 compounds are as named in Table B, i.e.,  $R_2$ ,  $R_1A$ , Y and X substituents are as defined in Table A, but they are bonded to the steroid nucleus shown in formula 7, which is the same as the formula 4 steroid nucleus, except that  $Q_3$  is  $-CH_2OH$



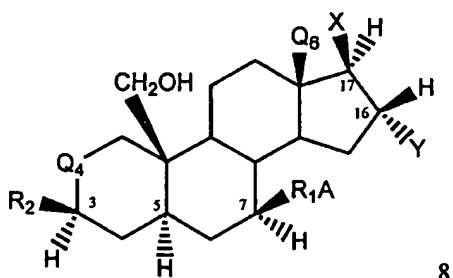
7.

Thus, the group 4 compound named 1.2.1.1 has the structure



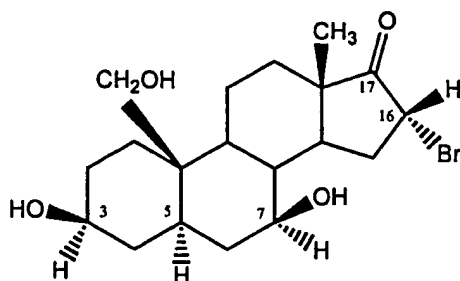
group 4, compound 1.2.1.1.

**Group 5.** Group 5 compounds are as named in Table B, i.e.,  $R_2$ ,  $R_1A$ , Y and X substituents are as defined in Table A, but they are bonded to the steroid nucleus shown in formula 8, which is the same as the formula 4 steroid nucleus, except that the 5-6 double bond is absent and hydrogen is present at the 5-position in the  $\alpha$ -configuration and  $Q_3$  is  $-CH_2OH$

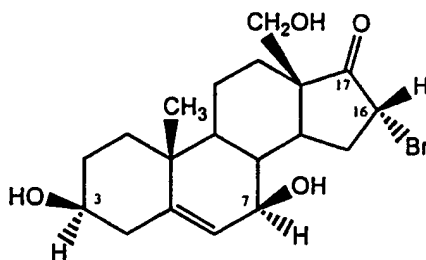


8.

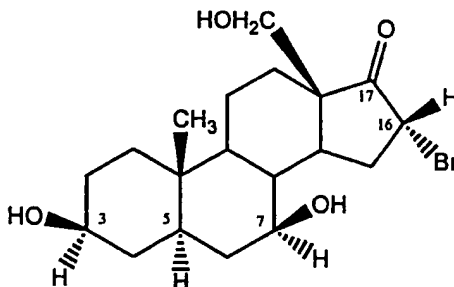
Thus, the group 5 compound named 1.2.1.1 has the structure



**Group 6.** Group 6 compounds are as named in groups 1-5, except that Q<sub>6</sub> in formulas 4-8 is -CH<sub>2</sub>OH instead of methyl. In group 6, there are 5 subgroups of group 6 compounds. The first subgroup, subgroup 6-1, has the same steroid nucleus with the substituents as defined for group 1 compounds while the second, subgroup 6-2, has the same steroid nucleus with the substituents as defined for group 2 compounds. Subgroups 6-3 through 6-5 have the same steroid nucleus with the substituents as defined for group 3 through 5 respectively. Thus, for example, the subgroup 6-1 compound named 1.2.1.1 has the structure



and the subgroup 6-2 compound named 1.2.1.1 has the structure



**Group 7.** Group 7 compounds are as named in groups 1-5, except that the Y moiety in formulas 4-8 is in the  $\beta$ -configuration instead of in the  $\alpha$ -configuration. Group 7 comprises 5 subgroups, wherein the compounds are named essentially as described for group 6 compounds, except that the Y group is in the  $\beta$ -configuration.

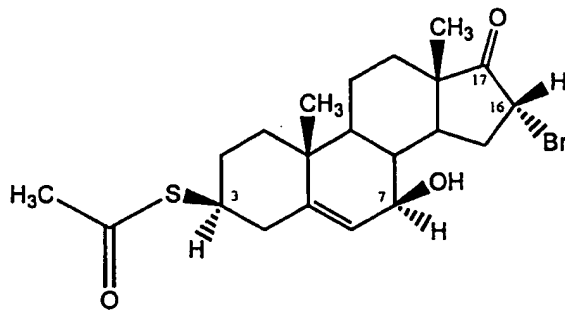
**Group 8.** Group 8 compounds are as named in groups 1-5, except that the X moiety in formulas 4-8 is in the  $\alpha$ -configuration instead of in the  $\beta$ -configuration. Group 8 comprises 5 subgroups, wherein the compounds are named essentially as described for group 6 compounds, except that the X group is in the  $\alpha$ -configuration.

5        **Group 9.** Group 9 compounds are as named in groups 1-5, except that the R<sub>2</sub> moiety in formulas 4-8 is in the  $\alpha$ -configuration instead of in the  $\beta$ -configuration. Group 9 comprises 5 subgroups, wherein the compounds are named essentially as described for group 6 compounds, except that the R<sub>2</sub> group is in the  $\alpha$ -configuration.

10       **Group 10.** Group 10 compounds are as named in groups 1-9, except that R<sub>2</sub> moieties 1 through 10 in Table A are replaced with the following moieties.

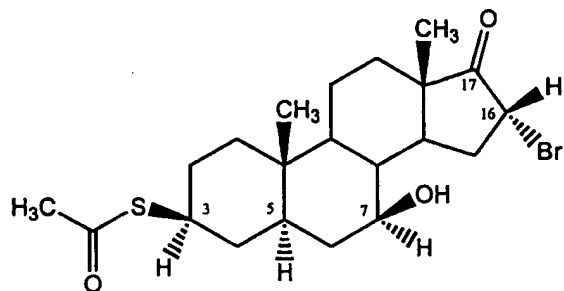
- 1 -S-C(O)-CH<sub>3</sub>
- 2 -S-C(O)-CH<sub>2</sub>-C<sub>6</sub>H<sub>5</sub>
- 3 -O-S(O)-O-CH<sub>3</sub>
- 4 -O-S(O)-O-CH<sub>2</sub>-C<sub>6</sub>H<sub>5</sub>
- 15 5 -O-S(O)(O)-O-CH<sub>3</sub>
- 6 -O-S(O)(O)-O-CH<sub>2</sub>-C<sub>6</sub>H<sub>5</sub>
- 7 -O-C(O)-NH-CH<sub>3</sub>
- 8 -O-C(O)-NH-C<sub>6</sub>H<sub>5</sub>
- 9 -O-C(S)-CH<sub>3</sub>
- 20 10 -O-C(S)-CH<sub>2</sub>-C<sub>6</sub>H<sub>5</sub>

Group 10 comprises 25 subgroups of compounds. The first, subgroup 10-1, has the same steroid nucleus with substituents as defined for group 1, except that the R<sub>2</sub> moieties or groups listed replace those in Table A above. The subgroup 10-1 compound named 1.2.1.1 has the structure

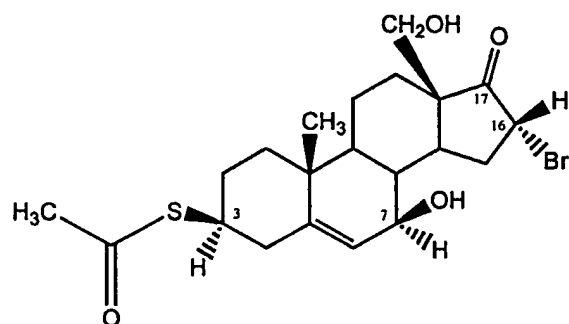


25

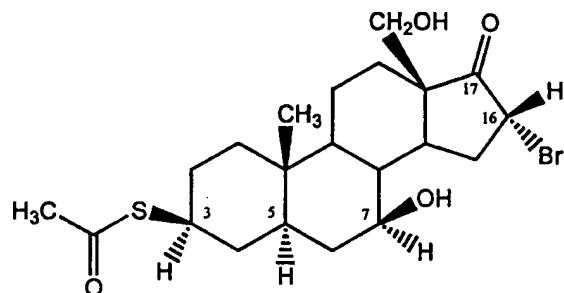
the subgroup 10-2 compound named 1.2.1.1 has the structure



the subgroup 10-6-1 compound named 1.2.1.1 has the structure



5 and the subgroup 10-6-2 compound named 1.2.1.1 has the structure



**Group 11.** Group 11 compounds are as named in groups 1-9, except that R<sub>2</sub> moieties 1 through 10 in Table A are replaced with the following moieties.

- |    |   |
|----|---|
| 10 | 1 -S-C(O)-CH <sub>2</sub> CH <sub>2</sub> -O-CH <sub>2</sub> CH <sub>3</sub>      |
|    | 2 -S-C(O)-CH <sub>2</sub> -C <sub>6</sub> H <sub>4</sub> OCH <sub>3</sub>         |
|    | 3 -O-S(O)-O-CH <sub>2</sub> CH <sub>2</sub> -O-CH <sub>2</sub> CH <sub>3</sub>    |
|    | 4 -O-S(O)-O-CH <sub>2</sub> -C <sub>6</sub> H <sub>4</sub> OCH <sub>3</sub>       |
|    | 5 -O-S(O)(O)-O-CH <sub>2</sub> CH <sub>2</sub> -O-CH <sub>2</sub> CH <sub>3</sub> |
| 15 | 6 -O-S(O)(O)-O-CH <sub>2</sub> -C <sub>6</sub> H <sub>4</sub> OCH <sub>3</sub>    |
|    | 7 -O-C(O)-NH-CH <sub>2</sub> CH <sub>2</sub> -O-CH <sub>2</sub> CH <sub>3</sub>   |
|    | 8 -O-C(O)-NH-C <sub>6</sub> H <sub>4</sub> OCH <sub>3</sub>                       |
|    | 9 -O-C(S)-CH <sub>2</sub> CH <sub>2</sub> -O-CH <sub>2</sub> CH <sub>3</sub>      |



**Group 12.** Group 12 compounds are as named in groups 1-9, except that R<sub>2</sub> moieties 1 through 10 in Table A are replaced with the following moieties.

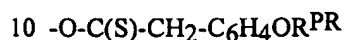
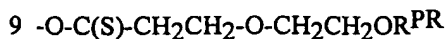
- 1 -S-C(O)-CH<sub>2</sub>CH<sub>2</sub>-O-CH<sub>2</sub>C(O)OH
- 5 2 -S-C(O)-CH<sub>2</sub>-C<sub>6</sub>H<sub>4</sub>F
- 3 -O-S(O)-O-CH<sub>2</sub>CH<sub>2</sub>-O-CH<sub>2</sub>C(O)OH
- 4 -O-S(O)-O-CH<sub>2</sub>-C<sub>6</sub>H<sub>4</sub>F
- 5 -O-S(O)(O)-O-CH<sub>2</sub>CH<sub>2</sub>-O-CH<sub>2</sub>C(O)OH
- 6 -O-S(O)(O)-O-CH<sub>2</sub>-C<sub>6</sub>H<sub>4</sub>F
- 10 7 -O-C(O)-NH-CH<sub>2</sub>CH<sub>2</sub>-O-CH<sub>2</sub>C(O)OH
- 8 -O-C(O)-NH-C<sub>6</sub>H<sub>4</sub>F
- 9 -O-C(S)-CH<sub>2</sub>CH<sub>2</sub>-O-CH<sub>2</sub>C(O)OH
- 10 -O-C(S)-CH<sub>2</sub>-C<sub>6</sub>H<sub>4</sub>F

**Group 13.** Group 13 compounds are as named in groups 1-9, except that R<sub>2</sub> moieties 1 through 10 in Table A are replaced with the following moieties.

- 1 -S-C(O)-CH<sub>2</sub>CH<sub>2</sub>-O-CH<sub>2</sub>CH<sub>2</sub>OH
- 2 -S-C(O)-CH<sub>2</sub>-C<sub>6</sub>H<sub>4</sub>CH<sub>3</sub>
- 3 -O-S(O)-O-CH<sub>2</sub>CH<sub>2</sub>-O-CH<sub>2</sub>CH<sub>2</sub>OH
- 4 -O-S(O)-O-CH<sub>2</sub>-C<sub>6</sub>H<sub>4</sub>CH<sub>3</sub>
- 20 5 -O-S(O)(O)-O-CH<sub>2</sub>CH<sub>2</sub>-O-CH<sub>2</sub>CH<sub>2</sub>OH
- 6 -O-S(O)(O)-O-CH<sub>2</sub>-C<sub>6</sub>H<sub>4</sub>CH<sub>3</sub>
- 7 -O-C(O)-NH-CH<sub>2</sub>CH<sub>2</sub>-O-CH<sub>2</sub>CH<sub>2</sub>OH
- 8 -O-C(O)-NH-C<sub>6</sub>H<sub>4</sub>CH<sub>3</sub>
- 9 -O-C(S)-CH<sub>2</sub>CH<sub>2</sub>-O-CH<sub>2</sub>CH<sub>2</sub>OH
- 25 10 -O-C(S)-CH<sub>2</sub>-C<sub>6</sub>H<sub>4</sub>CH<sub>3</sub>

**Group 14.** Group 14 compounds are as named in groups 1-9, except that R<sub>2</sub> moieties 1 through 10 in Table A are replaced with the following moieties.

- 1 -S-C(O)-CH<sub>2</sub>CH<sub>2</sub>-O-CH<sub>2</sub>CH<sub>2</sub>OR<sup>PR</sup>
- 2 -S-C(O)-CH<sub>2</sub>-C<sub>6</sub>H<sub>4</sub>OR<sup>PR</sup>
- 30 3 -O-S(O)-O-CH<sub>2</sub>CH<sub>2</sub>-O-CH<sub>2</sub>CH<sub>2</sub>OR<sup>PR</sup>
- 4 -O-S(O)-O-CH<sub>2</sub>-C<sub>6</sub>H<sub>4</sub>OR<sup>PR</sup>
- 5 -O-S(O)(O)-O-CH<sub>2</sub>CH<sub>2</sub>-O-CH<sub>2</sub>CH<sub>2</sub>OR<sup>PR</sup>
- 6 -O-S(O)(O)-O-CH<sub>2</sub>-C<sub>6</sub>H<sub>4</sub>OR<sup>PR</sup>
- 7 -O-C(O)-NH-CH<sub>2</sub>CH<sub>2</sub>-O-CH<sub>2</sub>CH<sub>2</sub>OR<sup>PR</sup>
- 35 8 -O-C(O)-NH-C<sub>6</sub>H<sub>4</sub>OR<sup>PR</sup>



**Group 15.** Group 15 compounds are as named in groups 1-9, except that R<sub>2</sub> moieties 1 through 10 in Table A are replaced with the following moieties.

- 5 1 -S-C(O)-CH<sub>2</sub>CH<sub>2</sub>-O-CH<sub>2</sub>CH<sub>2</sub>NHR<sup>PR</sup>  
 2 -S-C(O)-CH<sub>2</sub>-C<sub>6</sub>H<sub>3</sub>(OR<sup>PR</sup>)<sub>2</sub>  
 3 -O-S(O)-O-CH<sub>2</sub>CH<sub>2</sub>-O-CH<sub>2</sub>CH<sub>2</sub>NHR<sup>PR</sup>  
 4 -O-S(O)-O-CH<sub>2</sub>-C<sub>6</sub>H<sub>3</sub>(OR<sup>PR</sup>)<sub>2</sub>  
 5 -O-S(O)(O)-O-CH<sub>2</sub>CH<sub>2</sub>-O-CH<sub>2</sub>CH<sub>2</sub>NHR<sup>PR</sup>  
 10 6 -O-S(O)(O)-O-CH<sub>2</sub>-C<sub>6</sub>H<sub>3</sub>(OR<sup>PR</sup>)<sub>2</sub>  
 7 -O-C(O)-NH-CH<sub>2</sub>CH<sub>2</sub>-O-CH<sub>2</sub>CH<sub>2</sub>NHR<sup>PR</sup>  
 8 -O-C(O)-NH-C<sub>6</sub>H<sub>3</sub>(OR<sup>PR</sup>)<sub>2</sub>  
 9 -O-C(S)-CH<sub>2</sub>CH<sub>2</sub>-O-CH<sub>2</sub>CH<sub>2</sub>NHR<sup>PR</sup>  
 10 -O-C(S)-CH<sub>2</sub>-C<sub>6</sub>H<sub>3</sub>(OR<sup>PR</sup>)<sub>2</sub>

15 **Group 16.** Group 16 compounds are as named in groups 1-9, except that R<sub>2</sub> moieties 1 through 10 in Table are replaced with the following moieties.

- 1 -S-C(O)-(CH<sub>2</sub>)<sub>0-6</sub>-CH<sub>3</sub>  
 2 -S-C(O)-CH<sub>2</sub>-C<sub>6</sub>H<sub>5</sub>  
 3 -O-S(O)-O-(CH<sub>2</sub>)<sub>0-6</sub>-CH<sub>3</sub>  
 20 4 -O-S(O)-O-CH<sub>2</sub>-C<sub>6</sub>H<sub>5</sub>  
 5 -O-S(O)(O)-O-(CH<sub>2</sub>)<sub>0-6</sub>-CH<sub>3</sub>  
 6 -O-S(O)(O)-O-CH<sub>2</sub>-C<sub>6</sub>H<sub>5</sub>  
 7 -O-C(O)-NH-(CH<sub>2</sub>)<sub>0-6</sub>-CH<sub>3</sub>  
 8 -O-C(O)-NH-(CH<sub>2</sub>)<sub>0-6</sub>-C<sub>6</sub>H<sub>5</sub>  
 25 9 -O-C(S)-(CH<sub>2</sub>)<sub>0-6</sub>-CH<sub>3</sub>  
 10 -O-C(S)-CH<sub>2</sub>-C<sub>6</sub>H<sub>5</sub>

**Group 17.** Group 17 compounds are as named in groups 1-9, except that R<sub>2</sub> moieties 1 through 10 in Table A are replaced with the following moieties.

- 1 -S-C(O)-CH<sub>2</sub>CH<sub>2</sub>-(O-CH<sub>2</sub>CH<sub>2</sub>)<sub>1-50</sub>-H  
 30 2 -S-C(O)-CH<sub>2</sub>-C<sub>6</sub>H<sub>4</sub>OCH<sub>3</sub>  
 3 -O-S(O)-O-CH<sub>2</sub>CH<sub>2</sub>-(O-CH<sub>2</sub>CH<sub>2</sub>)<sub>1-50</sub>-H  
 4 -O-S(O)-O-CH<sub>2</sub>-C<sub>6</sub>H<sub>4</sub>OCH<sub>3</sub>  
 5 -O-S(O)(O)-O-CH<sub>2</sub>CH<sub>2</sub>-(O-CH<sub>2</sub>CH<sub>2</sub>)<sub>1-50</sub>-H  
 6 -O-S(O)(O)-O-CH<sub>2</sub>-C<sub>6</sub>H<sub>4</sub>OCH<sub>3</sub>  
 35 7 -O-C(O)-NH-CH<sub>2</sub>CH<sub>2</sub>-(O-CH<sub>2</sub>CH<sub>2</sub>)<sub>1-50</sub>-H

- 8 -O-C(O)-NH-C<sub>6</sub>H<sub>4</sub>OCH<sub>3</sub>
- 9 -O-C(S)-CH<sub>2</sub>CH<sub>2</sub>-(O-CH<sub>2</sub>CH<sub>2</sub>)<sub>1-50</sub>-H
- 10 -O-C(S)-CH<sub>2</sub>-C<sub>6</sub>H<sub>4</sub>OCH<sub>3</sub>

**Group 18.** Group 18 compounds are as named in groups 1-9, except that R<sub>2</sub> moieties 1 through 10 in Table A are replaced with the following moieties.

- 1 -O-C(O)-CH<sub>2</sub>CH<sub>2</sub>-(O-CH<sub>2</sub>CH<sub>2</sub>)<sub>1-50</sub>-H
- 2 -O-C(O)-CH<sub>2</sub>-C<sub>6</sub>H<sub>4</sub>OCH<sub>3</sub>
- 3 -O-C(O)-(CH<sub>2</sub>)<sub>0-6</sub>-CH<sub>3</sub>
- 4 -O-C(O)-CH<sub>2</sub>-C<sub>6</sub>H<sub>4</sub>NO<sub>2</sub>
- 10 5 -O-C(O)-CH<sub>2</sub>CH<sub>2</sub>-(O-CH<sub>2</sub>CH<sub>2</sub>)<sub>1-50</sub>-H
- 6 -O-C(O)-CH<sub>2</sub>-C<sub>6</sub>H<sub>5</sub>
- 7 -O-C(O)-CH<sub>2</sub>CH<sub>2</sub>-O-CH<sub>2</sub>CH<sub>3</sub>
- 8 -O-C(O)-C<sub>6</sub>H<sub>5</sub>
- 9 -O-C(O)-CH<sub>2</sub>CH<sub>2</sub>-S-CH<sub>2</sub>CH<sub>3</sub>
- 15 10 -O-C(O)-CH<sub>2</sub>-C<sub>6</sub>H<sub>4</sub>F

**Group 19.** Group 19 compounds are as named in groups 1-9, except that R<sub>2</sub> moieties 1 through 10 in Table A are replaced with the following moieties.

- 1 -O-CH<sub>2</sub>CH<sub>2</sub>-(O-CH<sub>2</sub>CH<sub>2</sub>)<sub>1-50</sub>-H
- 2 -O-CH<sub>2</sub>-C<sub>6</sub>H<sub>4</sub>OCH<sub>3</sub>
- 20 3 -O-(CH<sub>2</sub>)<sub>0-6</sub>-CH<sub>3</sub>
- 4 -O-CH<sub>2</sub>-C<sub>6</sub>H<sub>4</sub>NO<sub>2</sub>
- 5 -O-CH<sub>2</sub>CH<sub>2</sub>-(O-CH<sub>2</sub>CH<sub>2</sub>)<sub>1-50</sub>-H
- 6 -O-CH<sub>2</sub>-C<sub>6</sub>H<sub>5</sub>
- 7 -O-CH<sub>2</sub>CH<sub>2</sub>-O-CH<sub>2</sub>CH<sub>3</sub>
- 25 8 -O-C<sub>6</sub>H<sub>5</sub>
- 9 -O-CH<sub>2</sub>CH<sub>2</sub>-S-CH<sub>2</sub>CH<sub>3</sub>
- 10 -O-CH<sub>2</sub>-C<sub>6</sub>H<sub>4</sub>F

**Group 20.** Group 20 compounds are as named in groups 1-9, except that R<sub>2</sub> moieties 1 through 10 in Table A are replaced with the following moieties.

- 30 1 -C(O)-O-CH<sub>2</sub>CH<sub>2</sub>-(O-CH<sub>2</sub>CH<sub>2</sub>)<sub>1-50</sub>-H
- 2 -C(O)-O-CH<sub>2</sub>-C<sub>6</sub>H<sub>4</sub>OCH<sub>3</sub>
- 3 -C(O)-O-(CH<sub>2</sub>)<sub>0-6</sub>-CH<sub>3</sub>
- 4 -C(O)-O-CH<sub>2</sub>-C<sub>6</sub>H<sub>4</sub>NO<sub>2</sub>
- 5 -C(O)-O-CH<sub>2</sub>CH<sub>2</sub>-(O-CH<sub>2</sub>CH<sub>2</sub>)<sub>1-50</sub>-H
- 35 6 -C(O)-O-CH<sub>2</sub>-C<sub>6</sub>H<sub>5</sub>

7 -C(O)-O-CH<sub>2</sub>CH<sub>2</sub>-O-CH<sub>2</sub>CH<sub>3</sub>

8 -C(O)-O-C<sub>6</sub>H<sub>5</sub>

9 -C(O)-O-CH<sub>2</sub>CH<sub>2</sub>-S-CH<sub>2</sub>CH<sub>3</sub>

10 -C(O)-O-CH<sub>2</sub>-C<sub>6</sub>H<sub>4</sub>F

- 5           **Group 21.** Group 21 compounds are as named in groups 1-9, except that R<sub>2</sub> moieties 1 through 10 in Table A are replaced with the following moieties.

1 -C(O)-O-G12

2 -O-C(O)-G12

3 -C(O)-S-G12

- 10 4 -S-C(O)-G12

5 -C(S)-O-G12

6 -O-C(S)-G12

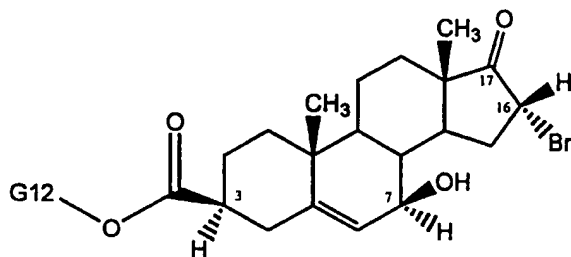
7 -O-C(O)-NH-G12

8 -NH-C(O)-O-G12

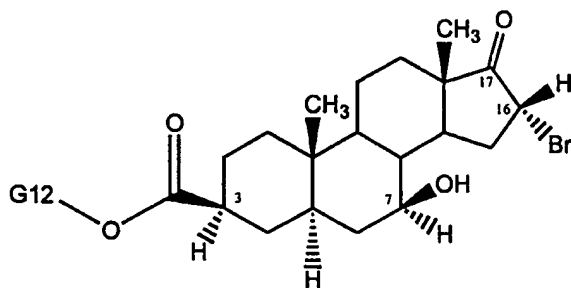
- 15 9 -C(O)-O-CH<sub>2</sub>-G12

10 -O-C(O)-CH<sub>2</sub>-G12

Thus, the group 21-1 compound named 1.2.1.1 has the structure

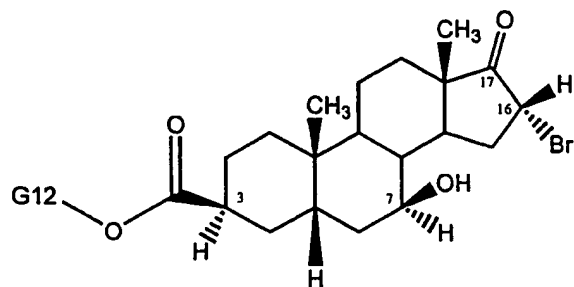


while the group 21-2 compound named 1.2.1.1 has the structure

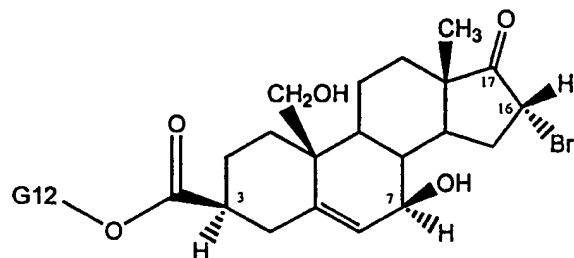


the group 21-3 compound named 1.2.1.1 has the structure

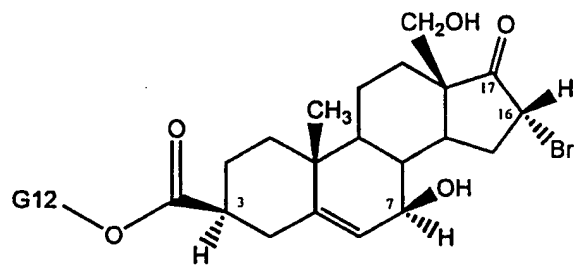




the group 21-4 compound named 1.2.1.1 has the structure

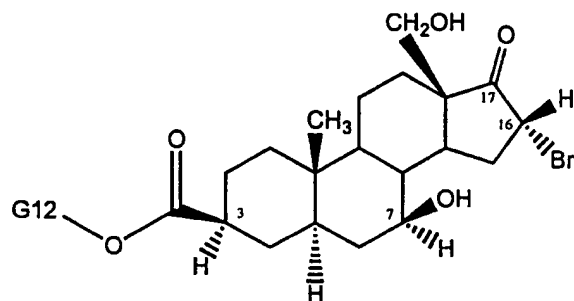


the group 21-6-1 compound named 1.2.1.1 has the structure

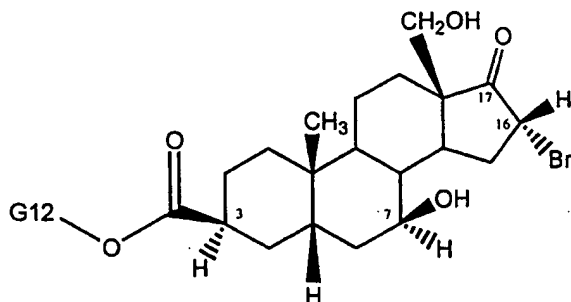


5

the group 21-6-2 compound named 1.2.1.1 has the structure



and the group 21-6-3 compound named 1.2.1.1 has the structure



G12 in Group 21 is an organic moiety comprising 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11 or 12 carbon atoms and 0, 1, 2, 3, 4, 5, 6, 7 or 8 independently selected O, S, N, P, or Si atoms, but, if a Si or P atom is present, only one Si or P is present, wherein the organic moiety is optionally selected from C<sub>1-12</sub> alkyl, C<sub>2-12</sub> alkenyl, C<sub>2-12</sub> alkynyl, aryl, a C<sub>2-9</sub> heterocycle or a substituted derivative of any of these comprising 1, 2, 3, 4 or more substituents, wherein each substituent is independently chosen and is selected from -O-, -S-, -NR<sup>RPR</sup> (including -NH-), -C(O)-, =O, =S, -N(R<sup>RPR</sup>)<sub>2</sub> (including -NH<sub>2</sub>), -C(O)OR<sup>RPR</sup> (including -C(O)OH), -OC(O)R<sup>RPR</sup> (including -O-C(O)-H), -OR<sup>RPR</sup> (including -OH), -SR<sup>RPR</sup> (including -SH), -NO<sub>2</sub>, -CN, -NHC(O)-, -C(O)NH-, -OC(O)-, -C(O)O-, -O-A8, -S-A8, -C(O)-A8, -OC(O)-A8, -C(O)O-A8, =N-, -N=, =N-OH, -OPO<sub>3</sub>(R<sup>RPR</sup>)<sub>2</sub>, -OSO<sub>3</sub>H<sub>2</sub> and halogen moieties or atoms, where each R<sup>RPR</sup> is -H, an independently selected protecting group or both R<sup>RPR</sup> together comprise a protecting group, and A8 is C<sub>1-8</sub> alkyl, C<sub>2-8</sub> alkenyl, C<sub>2-8</sub> alkynyl, C<sub>1-4</sub> alkyl-aryl (e.g., benzyl), aryl (e.g. phenyl) or C<sub>1-4</sub> alkyl-C<sub>2-9</sub> heterocycle. G12 moieties include -CH<sub>3</sub>, -C<sub>2</sub>H<sub>5</sub>, -C<sub>3</sub>H<sub>7</sub>, -C<sub>4</sub>H<sub>9</sub>, -C<sub>6</sub>H<sub>13</sub>, -CH<sub>2</sub>-C<sub>6</sub>H<sub>5</sub>, -C<sub>2</sub>H<sub>4</sub>-C<sub>6</sub>H<sub>5</sub>, -C<sub>3</sub>H<sub>6</sub>-C<sub>6</sub>H<sub>5</sub>, -C<sub>6</sub>H<sub>5</sub>, -CH<sub>2</sub>-heterocycle, -CH<sub>2</sub>-CH<sub>2</sub>-heterocycle and a heterocycle, any of which are substituted with one, two, three or more independently selected -O-, -S-, -F, -Cl, -Br, -I, -NH-, =O, -CN, -OCH<sub>3</sub>, -OC<sub>2</sub>H<sub>5</sub>, -OC<sub>4</sub>H<sub>9</sub>, -NO<sub>2</sub>, -NH<sub>2</sub>, -COOH, or -NH-C(O)- moieties.

Other embodiments include the use of any formula 4 compound or genus of formula 4 compounds that are named in any of the foregoing groups for any of the therapeutic or other applications described herein. This includes the use of any named formula 4 compound or genus for any of those applications wherein (i) R<sub>2</sub> is in the α-configuration, (ii) Q<sub>4</sub> is -CH(halogen)-, (iii) X is in the α-configuration and the -H at the 17-position is in the β-configuration, (iv) Y is in the β-configuration and the -H at the 16-position is in the α-configuration or (v) R<sub>1A</sub> is in the α-configuration and the -H at the 7-position is in the β-configuration.

Embodiments also include formula 1 compounds (e.g., formula 4 compounds) wherein R<sub>4</sub> is optionally substituted C<sub>1-8</sub> alkyl, optionally substituted C<sub>2-8</sub> alkenyl, optionally substituted C<sub>2-8</sub> alkynyl, optionally substituted aryl, optionally substituted heterocycle, optionally substituted C<sub>1-8</sub> alkyl-aryl, optionally substituted C<sub>1-8</sub> alkyl-heterocycle or optionally substituted -CH<sub>2</sub>-C<sub>1-8</sub> organic moiety (where the organic moiety is as described for esters), wherein any of the foregoing

ar independently substituted with 1, 2, 3, 4, 5 or 6 or more -O-, -S-, -NH-, -NH-C(O)- (i.e., -NH-C(O)- or -C(O)-NH-), =O, =NOH, -NO<sub>2</sub>, -CN, -F, -Cl, -Br, -I, -OH, -SH, or -NH<sub>2</sub>. Such R<sub>4</sub> moieties include -CH<sub>2</sub>-C<sub>1-6</sub> optionally substituted alkyl, -CH<sub>2</sub>-C<sub>2-6</sub> optionally substituted alkenyl, -CH<sub>2</sub>-C<sub>1-6</sub> optionally substituted aryl and -CH<sub>2</sub>-C<sub>2-9</sub> optionally substituted heterocycle.

5        Additional therapeutic embodiments. In accordance with a preferred aspect of the present invention, one or more compound of the present invention is administered to a patient who is suffering from AIDS in order to treat cryptosporidiosis in the patient and one or more additional compound are administered to the patient, such additional compound being a compound which is used for treatment of AIDS. Such compounds for treatment of AIDS are well known to those of skill in the art, and it is expected that additional compounds will be developed for treatment of AIDS. For example, protease inhibitors which are used in the treatment of AIDS include Invirase (saquinavir, RO-31-8959), made by Hoffmann-La Roche, Norvir (ritonavir, ABT538), made by Abbott, Crixivan (indinavir, MK-639), made by Merck, Viracept (nelfinavir, AG-1343), made by Agouron, VX-478 141W94, made by Glaxo-Wellcome-Vertex, KNI-272 (kynostatin), made by  
10        Nikko Kyoto Pharmaceutical and National Cancer Institute, U103373, made by Upjohn, CGP-53437, made by Ciba-Geigy, Hoe/Bay-793, made by Hoechst-Bayer, and SR-41476, made by Sanofi. In addition, reverse transcriptase inhibitors include AZT (Retrovir, zidovudine); ddI (Videx, didanosine); ddC (Hivid, zalcitabine); d4T (Zerit, stavudine); and 3TC (Epivir, Lamivudine). Also, HPA23 has reportedly been found to inhibit HIV replication.

20        The components of any of the combination therapies disclosed herein can be administered simultaneously (in a combination formulation), essentially simultaneously (e.g., administration of each compound a few minutes or a few hours apart), or can be administered sequentially, e.g., several days apart, or more than a week apart. For example, a compound of the present invention and a compound for the treatment of AIDS can be administered together, or essentially  
25        simultaneously, e.g., administration of each compound a few minutes or a few hours apart, or they can be administered sequentially, e.g., several days apart, or more than a week apart. All such variations in administration of the combination therapy are encompassed within the scope of the invention.

30        The invention also includes pharmaceutical formulations containing any such combination as described herein.

35        Articles of manufacture. The present invention also provides articles of manufacture comprising, for example, packaging material, at least one unit-dosage of a compound of the present invention (optionally together with one or more unit-dosage of a compound which can be administered in a combination therapy) and a label or package insert indicating that the compound can be used in a method disclosed herein.

In one embodiment, an article of manufacture comprises packaging material, at least one unit dose of a 17-ketosteroid (a formula 1 compound) and a label or package insert indicating that the 17-ketosteroid (a formula 1 compound) can be used in a method as described herein. The packaging material can be made from one or more generally known materials, e.g., foam, cardboard, fiberboard, polystyrene and polypropylene, and is of a size suitable to contain the compound(s) accompanying the packaging material. A label or package insert can be a tag or label secured to the packaging material, a label printed on the packaging material or a label inserted within the packaging material. The label indicates that the 17-ketosteroid can be used in a therapy as disclosed herein, e.g., in combination with a compound for the treatment of AIDS. The label can also indicate that the compound(s) have received approval from an official agency, for example, the U.S. Food and Drug Administration, for medical or veterinary use according to the method. The label may also indicate suitable administration routes, dosage regimen, and the like. If desired, the article may contain additional components such as at least one unit dose of a compound for treatment of AIDS.

Methods of administration and formulations. The dosage for a particular patient will vary depending on factors such as the overall health of the patient, the method, route and dose of administration and the severity of side effects (if any). Determination of the appropriate dose is made by the clinician using parameters known in the art. Generally, the dose begins with an amount somewhat less than the optimum dose and it is increased by small increments thereafter until the desired or optimum effect is achieved. The dosage of the compounds of the invention is suitably determined depending on the individual cases taking symptoms, age and sex of the subject and the like into consideration. With respect to the duration of treatment, it is typical for skilled clinicians to monitor patients in order to determine when inhibition is providing therapeutic benefit, and to determine whether to increase dosage, decrease dosage, discontinue therapy, resume therapy or alter therapy.

The therapeutically effective dosage of any specific compound will vary somewhat from compound to compound and patient to patient. As a general proposition, a dosage in the range of from about 0.1 to about 500 mg/kg will have therapeutic efficacy. Typically, a dosage in the range of from about 0.5 mg/kg to about 500 mg/kg will be employed. A daily dosage of a formula 1 compound will typically comprise about 10 to about 750 mg, usually about 20 to about 400 mg, which may be administered as a single dose or as two or more subdoses. Such doses or subdoses may be administered at one or more sites or by one or more than one route of administration. The duration for the treatment is usually once per day for a sufficient length of time for the patient to become asymptomatic, or for symptoms to abate noticeably. Depending upon the severity of the infection in the individual patient, this may last several days, weeks, or longer.

With regard to the frequency and duration of treatment, it is well known that it is within the skill of the ordinary physician to monitor a patient's condition and to make appropriate decisions with regard to discontinuing, interrupting and resuming treatments.

The dosages used in accordance with the invention are suitably determined depending on  
5 the individual cases taking symptoms, age and sex of the subject and the like into consideration. In addition, it is well known that it is within the skill of ordinary artisans to determine suitable dosages based on the above and other factors.

In accordance with the present method, a compound of the present invention may be administered orally, intramuscularly (IM), intravenously (IV), or subcutaneously (SC), with  
10 intravenous administration being especially preferred. Although other routes of administration can be used, it has been found that intravenous administration provides surprising effectiveness. Alternatively, the compound or salt may also be administered intravenously or intramuscularly as a liposomal suspension. The administration may also be in a cyclodextrin formulation (given orally, SC, IV or IM). Compounds of the invention and their pharmaceutically or physiologically,  
15 acceptable salts, are thus administered by any route suitable to the condition to be treated, including oral, rectal, nasal, topical (including ocular, buccal or sublingual), vaginal, parenteral (including subcutaneous, intramuscular, intravenous, intraperitoneal, intradermal, intrathecal, intradural and epidural) and pulmonary by aerosol. Generally, the compounds of the invention are administered parenterally, orally or topically. If an embodiment is not sufficiently orally  
20 bioavailable it can be administered by the other routes noted above.

Embodiments include formulations that comprise a liposome or lipid complex that comprises a formula 1 compound. Such formulations are prepared according to known methods, e.g., U.S. patents 4427649, 5043165, 5714163, 5744158, 5783211, 5795589, 5795987, 5798348, 5811118, 5820848, 5834016 and 5882678, all of which are incorporated herein by reference. The  
25 liposomes may optionally comprise an additional therapeutic or other agent(s). The liposomes can be delivered to a subject by any standard route, e.g., oral, aerosol or parenteral (e.g., SC, IV, IM).

Most often, the pharmaceutical compositions useful in the present invention will comprise a compound of Formula 1, or a pharmaceutically acceptable salt thereof, in any pharmaceutically acceptable carrier. If a solution is desired, water is the carrier of choice with respect to water-  
30 soluble compounds or salts. In other embodiments, an organic vehicle, such as glycerol, ethanol, propylene glycol, polyethylene glycol, DMSO, DMSO<sub>2</sub>, vegetable, mineral oils, ethanol, benzyl benzoate, or mixtures thereof, may be suitable. In general, the solutions in any instance should be sterilized in a suitable manner, preferably by filtration through a 0.22 micron filter. The compositions useful in the practice of the present invention may be provided in the form of vials,  
35 ampules, and the like.

In some embodiments, the formula 1 compound that is present in the compositions or that is used in the methods disclosed herein is completely dissolved in non-aqueous excipients.

However, in some embodiments, e.g., transient compositions or some formulations, the formula 1 compound is partially dissolved while the remaining portion is present as a solid, which can be a suspension or a colloid. In related embodiments, the formula 1 compound is incompletely dissolved and is present as a suspension or gel.

In addition to compounds of formula 1, or their salts, the pharmaceutical compositions may contain other additives, such as pH adjusting additives, in particular, agents such as acids, bases, or buffers, including sodium lactate, sodium acetate, and sodium gluconate. Further, such compositions may contain microbial preservatives, such as methylparaben, propylparaben, benzyl alcohol and benzyl benzoate. If a multiple use vial is supplied, the pharmaceutical composition should likewise include such a microbial preservative. The formulations may be, of course, lyophilized, using techniques well known in the art.

The formulations include those suitable for the foregoing administration routes. The formulations may conveniently be presented in unit dosage form and may be prepared by any of the methods well known in the art of pharmacy. Techniques, excipients and formulations generally are found in, e.g., *Remington's Pharmaceutical Sciences*, Mack Publishing Co., Easton, PA 1985, 17th edition, Nema et al., *PDA J. Pharm. Sci. Tech.* 1997 51:166-171, both of which are incorporated herein by reference. Methods to make invention formulations include the step of bringing into association a formula 1 compound with one or more excipients or carriers. In general, the formulations are prepared by uniformly and intimately bringing into association the formula 1 compound with liquid excipients or finely divided solid excipients or both, and then, if appropriate, shaping the product.

Formulations of the present invention suitable for oral administration may be presented as discrete units such as capsules, cachets or tablets each containing a predetermined amount of the formula 1 compound; as a powder or granules; as solution or a suspension in an aqueous liquid or a non-aqueous liquid; or as an oil-in-water liquid emulsion or a water-in-oil liquid emulsion. The formula 1 compound may also be presented as a bolus, electuary or paste.

A tablet may be made by compression or molding, optionally with one or more excipients.

Compressed tablets may be prepared by compressing in a suitable machine the formula 1 compound in a free-flowing form such as a powder or granules, optionally mixed with a binder, lubricant, inert diluent, preservative, surface active or dispersing agent. Molded tablets may be made by moulding in a suitable machine a mixture of the powdered compound moistened with an inert liquid diluent. The tablets may optionally be coated or scored and may be formulated so as to provide slow or controlled release of the formula 1 compound therein.

The oily phase of the emulsions of this invention may be constituted from known ingredients in a known manner. While the phase may comprise merely an emulsifier (otherwise known as an emulgent), it desirably comprises a mixture of at least one emulsifier with a fat or an oil or with both a fat and an oil. Preferably, a hydrophilic emulsifier is included together with a lipophilic emulsifier, which acts as a stabilizer. It is also preferred to include both an oil and a fat. Together, the emulsifier(s) with or without stabilizer(s) make up the emulsifying wax, and the wax together with the oil and fat make up the emulsifying ointment base which forms the oily dispersed phase of the cream formulations. Emulgents and emulsion stabilizers suitable for use in formulations comprising a formula 1 compound include Tween<sup>®</sup> 60, Span<sup>®</sup> 80, cetostearyl alcohol, benzyl alcohol, myristyl alcohol, glyceryl mono-stearate and sodium lauryl sulfate.

Formulations suitable for buccal administration include lozenges comprising a formula 1 compound in a flavored basis, usually sucrose and acacia or tragacanth; pastilles comprising the formula 1 compound in an inert basis such as gelatin and glycerin, or sucrose and acacia.

Formulations for rectal administration may be presented as a suppository with a suitable base comprising for example cocoa butter or a salicylate.

Formulations suitable for intrapulmonary or nasal administration will have a particle size for example in the range of 0.01 to 200 microns (including particle sizes in a range between 0.01 and 500 microns in increments of 0.1 microns such as 0.1, 0.2, 0.3, 0.4, 0.5, 1, 2, 5, 30 microns, 35 microns, etc.), which is administered by inhalation through the nasal passage or by inhalation through the mouth so as to reach the various bronchi or alveolar sacs. Formulations suitable for aerosol or dry powder administration may be prepared according to conventional methods and may be delivered with other therapeutic agents such as compounds heretofore used in the treatment or prophylaxis of *Toxoplasmosis* or *Cryptosporidium* infections. Inhalation therapy is readily administered by metered dose inhalers.

Formulations suitable for vaginal administration may be presented as pessaries, tampons, creams, gels, pastes, foams or spray formulations containing in addition to the formula 1 compound such carriers or excipients as are known in the art to be appropriate.

Formulations suitable for parenteral administration are sterile and include aqueous and non-aqueous injection solutions which may contain anti-oxidants, buffers, bacteriostats and solutes which render the formulation isotonic with the blood of the intended recipient; and aqueous and non-aqueous sterile suspensions which may include suspending agents and thickening agents. The formulations may be presented in unit-dose or multi-dose containers, for example sealed ampoules and vials with elastomeric stoppers, and may be stored in a freeze-dried (lyophilized) condition requiring only the addition of the sterile liquid carrier, for example water for injections, immediately prior to use. Extemporaneous injection solutions and suspensions may be prepared

from sterile powders, granules and tablets of the kind previously described. Unit dosage formulations will typically contain a daily dose or unit daily sub-dose, as recited above, or an appropriate fraction thereof, of a formula 1 compound.

In some embodiments, the formula 1 compounds will be administered on an intermittent basis. In these embodiments, the formula 1 compound, e.g., a dose that comprises about 5-500 mg of a formula 1 compound (typically about 50-400 mg), is administered to a subject for at least one day, followed by no dosing for at least one day (at least 24 hours), optionally followed by at least one more daily dose of, e.g., about 50-500 mg. Intermittent dosing methods may comprise dosing (1, 2, 3 or 4 doses per week) based on a weekly schedule, e.g., dosing on Monday, Wednesday and Friday, or on Tuesday, Thursday Saturday for about 1, 2, 3, 4, 6, 8 or more weeks, followed by periods of about 2, 3, 4, 5, 30, 45, 60, 90 or more days with no dosing, optionally followed by dosing again on Monday, Wednesday and Friday for about 1, 2, 3, 4, 6, 8 or more weeks. Weekly dosing methods may comprise administration of the formula 1 compound to a subject 1, 2, 3, 4 or 5 times per week for 1, 2, 3, 4, or more weeks.. In related embodiments, dosing may be administered to a subject daily for 2, 3, 4, 5, 6, 7 or more days, followed by a period of about 1, 2, 3, 4, 5, 7, 14, 30, 45 60, 90 or more days, optionally followed by another course of daily dosing.

In accordance with an especially preferred method of the present invention, a formulation prepared as described below is administered subcutaneously, by intramuscular injection or orally to a patient. (1) To a glass vessel, add 400 mg of one or more compound of the present invention and 2.5 mL of polyethylene glycol 300 and vortex for 1 minute to form a smooth, creamy liquid. (2) Add 2.5 mL of propylene glycol and vortex for 1 minute to form a uniform suspension. (3) Add 0.5 mL of benzyl benzoate and vortex for 1 minute to form a semi clear liquid. (4) Add 1.25 mL of absolute ethanol (99.5 %) and vortex to a clear and colorless solution. (5) Make up to 10 mL with propylene glycol. (6) Store at 10 - 25 degrees C. Avoid heating of any kind. Preferably, in such a formulation, the compound of the invention is bromine epiandrosterone or 16 $\alpha$ -bromoepiandrosterone.

To the extent not already indicated, it will be understood by those of ordinary skill in the art that any one of the various specific embodiments herein described and illustrated may be further modified to incorporate features shown in any of the other embodiments disclosed herein.

Therapeutic applications. For therapeutic applications, the compositions disclosed herein will typically comprise one or more compounds of formula 1, and, the methods disclosed herein will utilize such compositions, which will contain one, two or more of such compounds, usually one. While it is possible for the compounds of the invention to be administered as pure compounds it is preferable to present them as pharmaceutical formulations. The formulations of the present invention comprise at least one formula 1 compound together with one or more acceptable carriers



or excipients and optionally other therapeutic agents. The one or more carriers or excipients must be "acceptable" in the sense of being compatible with the other ingredients of the formulation and not deleterious to the patient.

It has been found that oral administration of bromine epiandrosterone is surprisingly  
5 effective for the treatment of infections of *Cryptosporidium* parasites and/or *Toxoplasma*, e.g., *T. gondii*, or *C. parvum*, in the gastrointestinal tracts of patients.

In other embodiments, a dosing regimen for a formula 1 compound will comprise the use of a relatively high induction dose, e.g., about 150-750 mg per day or about 150-750 mg per day using an intermittent dosing schedule (such as described herein), followed by lower maintenance  
10 dosing, e.g., about 50-250 mg per day or about 50-250 mg per day on an intermittent dosing schedule. These embodiments may further comprise treatment with another treatment as described herein.

Parenteral formulations may comprise a cyclodextrin, e.g., an  $\alpha$ -cyclodextrin, a  $\beta$ -cyclodextrin (e.g.,  $\beta$ -hydroxypropylcyclodextrin) or a  $\gamma$ -cyclodextrin, which are typically employed  
15 in aqueous formulations, which optionally comprise one or more of a buffer, a salt (NaCl, etc.) to, e.g., render the solution isotonic, a bacteriostat or other excipients as known in the art and a formula 1 compound at a concentration of, e.g., about 5-25 mg/mL, typically about 10-20 mg/mL. Parenteral formulations that comprise a formula 1 compound and one or more excipients may be diluted into, e.g., sterile saline and infused into a subject. Parenteral formulations are typically  
20 administered by, e.g., intravenous, topical or oral delivery to a subject such as a human. For non-aqueous formulations, one or more solvents such as propylene glycol, a PEG, e.g., PEG 300 or PEG 400, ethanol, and benzyl benzoate may be employed. Typical aqueous and non-aqueous formulations will contain about 5 to about 400 mg/mL of a formula 1 compound, usually about 10 to about 200 mg/mL. Such parenteral formulations may be delivered orally, or by intramuscular,  
25 intravenous or subcutaneous injection.

In preparing compositions that comprise a formula 1 compound (and optionally one or more excipients), one may optionally mill or otherwise granulate the compound to obtain a desired particle size, before or after the formula 1 compound is contacted with one or more excipients. For example, one may mill a formula 1 compound such as 16 $\alpha$ -bromoepiandrosterone, to obtain an  
30 average particle size (or diameter) of about 0.5-25  $\mu$ M or about 1-10  $\mu$ M (e.g., about 2, 5 or 10  $\mu$ M average particle size or diameter) before contacting the milled formula 1 compound with a liquid or solid excipient. Milled formula 1 compound is useful to facilitate dissolution or suspension of the formula 1 compound in one or more liquid excipients (e.g., a PEG such as PEG 300, propylene glycol or benzyl benzoate) or to facilitate uniformly distributing drug substance when the milled  
35 compound is contacted with one or more solid excipients (e.g., a filler, a binder or a lubricant).

The compositions and formulations disclosed herein are useful in the treatment of, or ameliorate one or more symptoms associated with, the conditions or infections disclosed herein. These compositions and formulations may also be used to treat, or ameliorate one or more symptoms associated with, a retroviral infection such as a HIV1 or HIV2 infection in humans, or Malaria in humans. As used herein, phrases such as "amelioration of one or more symptoms associated with" means that such compounds or formulations may be used to reduce replication of an infectious agent or to reduce the number of infectious agents that are present in a subject or to ameliorate one or more symptoms associated with, or caused by, the condition or infection (e.g., reduced fever, a shortened duration or level of pain, or a noticeable reduction of or elimination of diarrhea or fatigue).

In addition to the ingredients particularly mentioned above the formulations of this invention may include other agents conventional in the art having regard to the type of formulation in question, for example those suitable for oral administration may include flavoring or coloring agents.

The present invention further provides veterinary compositions comprising at least one formula 1 compound together with a veterinary carrier therefor. Also, the formula 1 compound may be present in the animal's feed or water. Excipients for veterinary applications may include compounds, e.g., small amounts of chloroform, that may not be generally suitable for human use.

Veterinary carriers are materials useful for the purpose of administering the composition to cats, dogs, horses, mice, rats, hamsters, rabbits and other animals and may be solid, liquid or gaseous materials that are otherwise inert or acceptable in the veterinary art and are compatible with the formula 1 compound. These veterinary compositions may be administered orally, parenterally or by any other desired route, e.g., as described herein. Veterinary carriers may include compounds that are not generally suitable for human applications, e.g., small amounts of chloroform.

Embodiments of formula 1 compounds include or exclude any subset of compounds within the definition of formula 1, provided that at least one compound remains. For example, a subset of formula 1 compounds that are generally preferred and are usually included, for example are aqueous or nonaqueous formulations comprising 16 $\alpha$ -bromoepiandrosterone. A subset compounds or applications for compounds that are optionally excluded from formula 1 compounds or their uses in any embodiment or claim herein comprises, e.g., the use of one or more compounds (or their use) that are disclosed in one or more prior art references or publications, to the extent that the disclosed compounds or uses renders any claim or embodiment unpatentable for novelty, obviousness and/or inventive step reasons.

In other embodiments, a formula 1 compound may be linked to an oligonucleotide or an oligonucleotide analog, e.g., to facilitate delivery of the oligonucleotide or analog into cells. Typically the formula 1 compound will be linked to the steroid nucleus through a terminal hydroxyl group at a 5', 3' or 2' position of the oligonucleotide. Oligonucleotides and analogs of  
5 oligonucleotides are known and have been described, e.g., U.S. patents 4725677, 4973679, 4997927, 4415732, 4458066, 5047524, 4959463, 5212295, 5386023, 5489677, 5594121, 5614622, 5624621; and PCT publication Nos. WO 92/07864, WO 96/29337, WO 97/14706, WO 97/14709, WO 97/31009, WO 98/04585, WO 98/04575, all of which are incorporated herein by reference.

Synthesis methods. In general, the compounds employed in the present invention in  
10 general may be synthesized in manners known and readily understood by those skilled in the art. Therefore, there is no need to explain in great detail the methodology used for the synthesis of most such compounds.

Formula 1 compounds that comprise a thioacetal moiety, sulfate ester, sulfite ester, carbamate or thioester moiety at R<sub>2</sub> (the 3-position) are prepared essentially according to methods  
15 known in the art. Suitably protected intermediates will be used as is apparent. See, for example, U.S. patent 5198432; European patent publications EP 576915 and EP 576914; C. Christiana et al., *J. Chem. Soc. Chem. Commun.* 1991 vol 22, C. Christiana et al., *J. Chem. Soc. Chem. Commun.* 1991 19:1403-1405, H.N. Abramson et al., *J. Pharm. Sci.* 1977 66:602-603, E.J. Corey et al., *J. Am. Chem. Soc.* 1996 118:8765-8766, A.G.M. Barrett et al., *J. Org. Chem.* 1989 54:227, D.H.R.  
20 Barton et al., *J. Chem. Soc. Perkin Trans. I* 1976 19:2112-2116, D.H.R. Barton et al., *J. Chem. Soc. Perkin Trans. I* 1975 16:1574-1585 and W.T. Smith et al., *Trans. Kentucky Acad. Sci.* 1984 45:76-77, all of which are incorporated herein by reference.

Enumerated embodiments. Aspects of the invention include the following enumerated  
25 embodiments, which further illustrate the invention and preferred aspects thereof or related subject matter.

1. A method of treating cryptosporidiosis in a patient in need of such treatment, comprising administering to said patient an effective amount of at least one compound of the present invention.

2. A method as recited in embodiment 1, wherein said patient is also infected with a  
30 retrovirus or is suffering from AIDS.

3. A method as recited in embodiment 2, further comprising administering to said patient at least one compound for treatment of AIDS.

4. A method as recited in embodiment 3, wherein said at least one compound of the present  
inv ntion and said at least one compound for the treatment of AIDS are administered  
35 simultaneously.

5. A method as recited in embodiment 3, wherein said at least one compound of the present invention and said at least one compound for the treatment of AIDS are administered sequentially.

6. A method as recited in any one of embodiments 1 - 5, wherein said patient is a mammal.

7. A method as recited in embodiment 6, wherein said patient is a human, a primate or a  
5 feline.

8. A method as recited in any one of embodiments 1 - 7, wherein said administering is by oral ingestion.

9. A method as recited in any one of embodiments 1 - 7, wherein said administering is by subcutaneous.

10. A method as recited in any one of embodiments 1 - 9, wherein said compound of the invention is bromine epiandrosterone or 16 $\alpha$ -bromoepiandrosterone.

11. A method as recited in any one of embodiments 1 -10, wherein said compound of the invention is contained in a formulation prepared by (1) combining said compound of the present invention and polyethylene glycol and vortexing to form a smooth, creamy liquid, (2) adding  
15 additional propylene glycol and vortexing to form a uniform suspension, (3) adding benzyl benzoate and vortexing to form a semi clear liquid, (4) adding ethanol and vortexing to a clear and colorless solution; and (5) optionally adding more propylene glycol.

12. A method of treating toxoplasmosis in a patient in need of such treatment, comprising administering to said patient an effective amount of at least one compound selected from the group  
20 consisting of the compounds of the present invention.

13. A method as recited in embodiment 12, wherein said patient is also infected with a retrovirus or is suffering from AIDS.

14. A method as recited in embodiment 13, further comprising administering to said patient at least one compound for treatment of AIDS.

25 15. A method as recited in embodiment 14, wherein said at least one compound of the present invention and said at least one compound for the treatment of AIDS are administered simultaneously.

16. A method as recited in embodiment 14, wherein said at least one compound of the present invention and said at least one compound for the treatment of AIDS are administered  
30 sequentially.

17. A method as recited in any one of embodiments 12 - 16, wherein said patient is a mammal.

18. A method as recited in embodiment 17, wherein said patient is a human, a primate or a feline.

19. A method as recited in any one of embodiments 12 - 18, wherein said administering is by oral ingestion.

20. A method as recited in any one of embodiments 12 - 18, wherein said administering is by subcutaneous or intramuscular injection.

5        21. A method as recited in any one of embodiments 12 - 20, wherein said compound of the invention is bromine epiandrosterone.

22. A method as recited in any one of embodiments 12-21, wherein said compound of the invention is contained in a formulation prepared by (1) combining said compound of the present invention and polyethylene glycol and vortexing to form a smooth, creamy liquid, (2) adding  
10 additional propylene glycol and vortexing to form a uniform suspension, (3) adding benzyl benzoate and vortexing to form a semi clear liquid, (4) adding ethanol and vortexing to a clear and colorless solution; and (5) optionally adding more propylene glycol.

23. A composition comprising at least one of the compounds of the present invention, and at least one compound for treatment of HIV infection or for the treatment of AIDS.

15        24. A kit comprising one or more unit dosages of at least one of the compounds of the present invention, and one or more unit dosages of at least one compound for treatment of HIV infection or for the treatment of AIDS.

25. The method of any of embodiments 1-24 wherein the compound of the invention is a formula 1 compound or a metabolite thereof.

20        26. The method of embodiment 25 wherein the formula 1 compound is a compound named in compound groups 1-21, or in any formula 1 (e.g., any formula 4) compound or genus disclosed or named herein, or a metabolite of any of these.

27.        A composition comprising 16 $\alpha$ -bromoepiandrosterone, and 2, 3, 4 or 5 excipients selected from polyethylene glycol, dehydrated ethanol, benzyl benzoate, benzyl alcohol and  
25 propylene glycol, wherein the composition comprises less than about 3% v/v, or less than about 1% v/v, or less than about 0.5% v/v of water, or less than about 0.1% v/v of water.

28.        The composition of embodiment 27 wherein the composition comprises (i) 16 $\alpha$ -bromoepiandrosterone at a concentration of about 45-55 mg/mL, (ii) 20-30% v/v polyethylene glycol 300, polyethylene glycol 400 or a mixture of polyethylene glycol 300 and 400, (iii) 10-15%  
30 v/v dehydrated ethyl alcohol, 2.5-7.5% v/v benzyl benzoate, and (iv) 55-60% v/v propylene glycol.

29.        The composition of embodiment 28 wherein the composition comprises 16 $\alpha$ -bromoepiandrosterone at a concentration of about 50 mg/mL, about 25% v/v polyethylene glycol 300, about 12.5% v/v dehydrated ethyl alcohol, about 5% v/v benzyl benzoate, about 57.5% v/v propylene glycol and less than about 0.5% v/v water.

30. The composition of embodiment 27 wherein the composition comprises 16 $\alpha$ -bromoepiandrosterone at a concentration of about 50-105 mg/mL, about 27-33% w/w benzyl benzoate, about 27-33% w/w polyethylene glycol 300, about 25-30% w/w propylene glycol and about 1-3% w/w benzyl alcohol.
- 5 31. The composition of embodiment 30 wherein the composition comprises 16 $\alpha$ -bromoepiandrosterone at a concentration of about 100 mg/mL (about 10% w/w), about 30.4% w/w benzyl benzoate, about 30.7% w/w polyethylene glycol 300, about 28% w/w propylene glycol and benzyl alcohol about 1.9% w/w.
- 10 32. A product produced by the process of contacting 16 $\alpha$ -bromoepiandrosterone and a liquid excipient, wherein the product contains less than about 3% water, provided that the liquid excipient is not chloroform, dimethylsulfoxide, olive oil, or a vegetable oil.
33. The product of embodiment 32 wherein the liquid excipient is polyethylene glycol, dehydrated ethanol, benzyl benzoate, benzyl alcohol and propylene glycol, wherein the product comprises less than about 3% v/v, or less than about 1% v/v, or less than about 0.5% v/v of water.
- 15 34. The use of a formula 1 compound for making a medicament for the treatment of an infection caused by one or more *Toxoplasma* or *Cryptosporidiosis* parasites in a subject.
35. The use of embodiment 34 wherein the formula 1 compound is a compound named in compound groups 1-21 or a metabolite thereof.
- 20 36. A method comprising administering an effective amount of a composition of any of embodiments 27-31 to a subject having, or susceptible to, a *Toxoplasma* or *Cryptosporidium* infection.
37. The method of embodiment 36 wherein the subject is a human and the human is optionally coinfecting with a retrovirus (e.g., HIV1 or HIV2).
- 25 38. A method to ameliorate or reduce one or more symptoms associated with a *Toxoplasma* or *Cryptosporidium* infection in a subject, or to reduce replication of a *Toxoplasma* or *Cryptosporidium* infection in a subject infected with a *Toxoplasma* or *Cryptosporidium* parasite, comprising administering to the subject an effective amount of a compound of formula 1.
- 30 39. The method of embodiment 38 wherein the formula 1 compound is a compound or within a genus of compounds as disclosed herein, e.g., a compound or genus named in compound groups 1-21 or in the claims as originally filed, or the formula 1 compound is present in a composition comprising one or more pharmaceutical excipients, e.g., any of the formulations disclosed or described herein.
- 35 40. A composition comprising a formula 1 compound wherein the formula 1 compound is a compound or within a genus of compounds as disclosed herein, e.g., a compound or genus named in compound groups 1-21 or in the claims as originally filed, and at least one excipient and a local

anesthetic, wherein the local anaesthetic is optionally selected from procaine, benzocaine and lidocaine.

41. A product produced by the process of contacting a compound of formula 1, e.g., any compound named in compound groups 1-21, and a first excipient with a second excipient wherein the product optionally further comprises a local anesthetic, wherein the local anaesthetic is optionally selected from procaine, benzocaine and lidocaine.

42. A product produced by the process of contacting a compound of formula 1, e.g., any compound named in compound groups 1-21, and a first nonaqueous liquid excipient with a second nonaqueous liquid excipient wherein the product comprises less than about 3% w/w water, or less than about 0.5% w/w water, or less than about 0.1% w/w water, and wherein the first or the second nonaqueous liquid excipient optionally excludes one or more of dimethylsulfoxide, chloroform, dioxane, a vegetable oil and olive oil, and wherein the product optionally further comprises a local anesthetic, wherein the local anaesthetic is optionally selected from procaine, benzocaine and lidocaine.

43. A method comprising administering an effective amount of the composition of embodiment 40 or the product of embodiments 41 or 42 to a subject having an infection or condition described herein, e.g., a *Toxoplasma* or *Cryptosporidium* parasite infection, whereby the infection or condition, or a symptom thereof, is eliminated, reduced, treated, improved or ameliorated.

44. The method of embodiment 43 wherein the formula 1 compound is 16 $\alpha$ -haloepiandrosterone or 16 $\alpha$ -halodehydroepiandrosterone.

#### EXAMPLES

The following examples further illustrate the invention and are not to be construed as limiting the invention.

**Example 1. Human clinical trial.** To a patient who had suffered two years continuously from diarrhea resulting from cryptosporidiosis, bromine epiandrosterone was administered once a day. After three days of such administration, the patient did not suffer from diarrhea.

**Example 2. 16 $\alpha$ -Bromoepiandrosterone formulation 1.** Two lots of a non-aqueous formulation was made at a 16 $\alpha$ -bromoepiandrosterone ("BrEA") concentration of 50 mg/mL in 25% polyethylene glycol 300, 12.5% dehydrated ethyl alcohol, 5% benzyl benzoate, and 57.5% propylene glycol, hereafter "formulation 1", as follows. BrEA was obtained from Procyte, Inc.

The remaining excipients are shown below.

Excipient	Specification	Supplier Lot No.	Final Product Concentration
Propylene glycol	USP	Arco Chemical HOC-61220-01104	57.5% (v:v)
Polyethylene glycol 300	NF	Union Carbide 695752	25% (v:v)
Dehydrated alcohol (ethanol)	USP	McCormick Distilling 97K10	12.5% (v:v)
Benzyl benzoate	USP	Spectrum Pharmaceuticals MG025	5% (v:v)

The formulation was prepared by suspending BrEA in polyethylene glycol 300, and sequentially adding propylene glycol, benzyl benzoate, and dehydrated ethyl alcohol to form a solution, which was diluted to the final desired volume with additional propylene glycol. The procedure is described below.

The calculated amount of polyethylene glycol 300 was added to a compounding vessel. Then, while mixing, the calculated amount of BrEA was added to the vessel, and mixed for at least 5 minutes to form a smooth, creamy liquid. Propylene glycol was added to the vessel, and mixed for a minimum of 5 minutes to form a uniform suspension. The calculated amount of benzyl benzoate is added to the vessel, and mixed for approximately 5 minutes to form a translucent liquid suspension. Dehydrated alcohol was added to the vessel, and mixed for approximately 5 minutes to form a clear, colorless solution. Propylene glycol was then added to achieve the desired final formulation, and mixed for approximately 5 minutes. The drug solution was transferred to a volume-dispensing device set to deliver 1.2 mL per vial. Under nitrogen pressure, the solution was filtered through two 0.2 µm polyvinylidene fluoride filters in series before dispensing into 2 cc amber glass vials. The vials were capped with Teflon-coated, butyl-rubber stoppers and crimp sealed.

Materials used in the product vials are listed below.

Material	Source	Product Code	Description
Vial	Wheaton	2702-B51BA	Tubing vial, 2 mL/13 mm, glass, type 1 amber
Stopper	Omniflex	V9239 FM257/2	13 mm, Teflon coated, butyl rubber stopper
Seal	West	4107	Flip seal, 13 mm, mist gray bridge



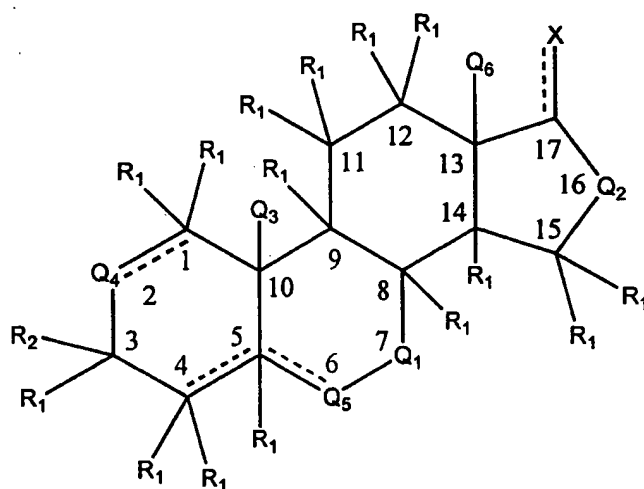
**Example 3. BrEA formulation 2.** A formulation containing 100 mg/mL of BrEA, 9% w/w, in benzyl benzoate (USP) 30.4% w/w, polyethylene glycol 300 (NF) 30.7% w/w, propylene glycol (USP), qs, about 28% w/w and benzyl alcohol (NF) 1.9% w/w, hereafter "formulation 2", was prepared as follows. A desired amount of BrEA (1.0 kg) was suspended in PEG 300 (about 5 3.0 L) in a compounding vessel and mixed for at least 5 minutes at room temperature to form a smooth creamy liquid. The needed amount of propylene glycol (about 1.5 L) was then added and mixing was continued for at least 5 minutes to form a uniform suspension. Benzyl benzoate (about 3.0 L) was then added and the vessel contents were mixed for about 5 minutes to form a translucent suspension. Benzyl alcohol (about 200 mL) was then added and the mixing was continued for 10 about 5 minutes to form a clear, colorless solution. Propylene glycol was then added to achieve the desired final formulation volume (about 1.5 L) and mixing was continued for about 5 minutes. The drug solution was transferred to a volume-dispensing device, which was set to deliver 1.2 mL per vial (2 mL, glass, type 1 amber vials). The formulation was filtered under nitrogen pressure (about 3 atm) through two 0.2  $\mu$ m polyvinylidene fluoride filters in series. The vials were capped using 15 Teflon-coated, butyl rubber stoppers and then crimp sealed essentially as described in example 2. The vials were stored in the dark at reduced temperature (about 2-8°C).

The foregoing detailed description has been provided for a better understanding of the invention only and no unnecessary limitation should be understood therefrom as some modifications will be apparent to those skilled in the art without deviating from the spirit and scope 20 of the appended claims.

## CLAIMS

What is claimed is:

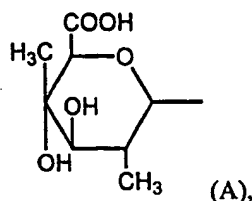
1. A method to treat or prevent a *Toxoplasma* or *Cryptosporidium* infection in a subject, or to ameliorate or reduce one or more symptoms of a *Toxoplasma* or *Cryptosporidium* infection, comprising administering to a subject an effective amount of a compound having formula 1,



1

wherein

- Q<sub>1</sub> is -C(R<sub>1</sub>)<sub>2</sub>- or -C(O)-;  
 10 Q<sub>2</sub> is -C(R<sub>1</sub>)<sub>2</sub>-, -C(R<sub>1</sub>)(Y)-, -C(Y)- or -CH<sub>2</sub>-CH<sub>2</sub>-;  
 Q<sub>3</sub> is -H or -C(R<sub>1</sub>)<sub>3</sub>-;  
 Q<sub>4</sub> is -C(R<sub>1</sub>)<sub>2</sub>-, -C(O)-, hydroxyvinylidene or methyl methylene;  
 Q<sub>5</sub> is -C(R<sub>1</sub>)<sub>2</sub>- or -C(O)-;  
 X and Y independently are -OH, -H, lower alkyl, -O-C(O)-R<sub>5</sub>,  
 15 -C(O)-OR<sub>5</sub>, halogen or =O;  
 each R<sub>1</sub> independently is -H, halogen, -OH, C<sub>1-6</sub> alkoxy, or C<sub>1-6</sub> alkyl;  
 R<sub>2</sub> is -H, -OH, halogen, C<sub>1-6</sub> alkyl, C<sub>1-6</sub> alkoxy, -OR<sub>3</sub>, an ester, a thioester, a thioacetal, a sulfate ester, a sulfonate ester or a carbamate or R<sub>2</sub>, together with the R<sub>1</sub> that is bonded to the same carbon atom is =O;  
 20 R<sub>3</sub> is -S(O)(O)-OM, -S(O)(O)-O-CH<sub>2</sub>-CH(O-C(O)-R<sub>6</sub>)-CH<sub>2</sub>-O-C(O)-R<sub>6</sub>,  
 -P(O)(O)-O-CH<sub>2</sub>-CH(O-C(O)-R<sub>7</sub>)-CH<sub>2</sub>-O-C(O)-R<sub>7</sub>, a glucuronide group of structure (A)

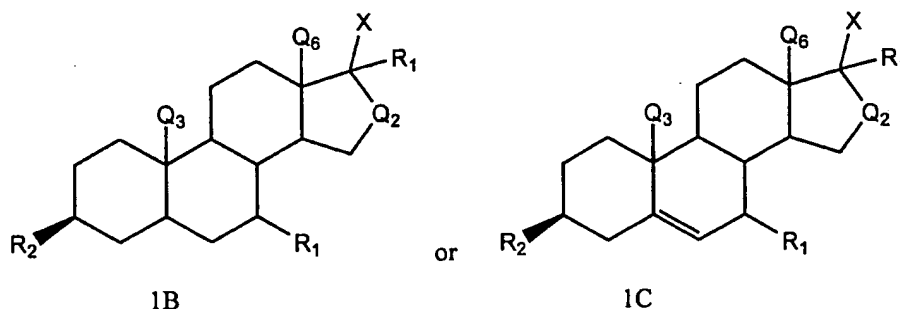


or R<sub>3</sub> is C<sub>1-18</sub> alkyl, C<sub>2-18</sub> alkenyl, C<sub>2-18</sub> alkynyl, a C<sub>1-18</sub> ester or a C<sub>1-18</sub> thioester, where any of the foregoing C<sub>1-18</sub> or C<sub>2-18</sub> moieties are optionally substituted at one or more hydrogen atoms with one or more independently selected -OR<sup>PR</sup>, -NHR<sup>PR</sup>, or -SR<sup>PR</sup>, groups, or R<sub>3</sub> is a C<sub>1-18</sub> fatty acid, C<sub>2-10</sub> alkynyl, (J)<sub>n</sub>-phenyl-C<sub>1-5</sub>-alkyl, (J)<sub>n</sub>-phenyl-C<sub>2-5</sub>-alkenyl;

- 5        each R<sub>5</sub> independently is straight or branched C<sub>1-14</sub> alkyl;
- each R<sub>6</sub> independently is C<sub>1-14</sub> straight or branched alkyl; and
- each R<sub>7</sub> independently is C<sub>1-14</sub> straight or branched alkyl or a glucuronide group of structure (A);
- each R<sup>PR</sup> independently is -H or an independently selected protecting group;
- 10        n is 0, 1, 2 or 3;
- each J independently is halogen, C<sub>1-4</sub> alkyl, C<sub>1-4</sub> alkenyl, C<sub>1-4</sub> alkoxy, carboxy, nitro, sulfate, sulfonyl, a C<sub>1-6</sub> carboxyl ester or a C<sub>1-6</sub> sulfate ester;
- M is hydrogen, sodium, -S(O)(O)-O-CH<sub>2</sub>-CH(O-C(O)-R<sub>6</sub>)-CH<sub>2</sub>-O-C(O)-R<sub>6</sub>, -P(O)(O)-O-CH<sub>2</sub>-CH(O-C(O)-R<sub>7</sub>)-CH<sub>2</sub>-O-C(O)-R<sub>7</sub> or a glucuronide group of structure (A); and
- 15        the dotted lines represent an optional double bond, provided that there are not double bonds at both the 4-5 and 5-6 positions and provided that when a double bond is present, zero or 1 R<sub>1</sub> group is bonded to carbon atoms at the 1-, 2-, 4-, 5-, 6- or 17 positions so that these carbon atoms are tetravalent; and
- the salts, stereoisomers, positional isomers, metabolites, analogs, precursors, hydrates,
- 20        tautomers, ionized forms and solvates thereof.
2.        The method of claim 1 wherein the *Toxoplasma* or *Cryptosporidium* infection is a *Toxoplasma* infection.
3.        The method of claim 2 wherein the formula 1 compound is one or more compounds selected from compound groups 1-21.
- 25        4.        The method of claim 2 wherein the *Toxoplasma* or *Cryptosporidium* infection is an infection caused by one or more of *Cryptosporidium parvum*, and *Toxoplasma gondii*.
5.        The method of claim 4 wherein the formula 1 compound is one or more compounds selected from compound groups 1-21.
6.        The method of claim 5 wherein the subject is a human or a primate.
- 30        7.        The method of claim 6 wherein the formula 1 compound is one or more compounds selected from compound groups 1-21.
8.        The method of claim 7 wherein the formula 1 compound is 16 $\alpha$ -bromo-3 $\beta$ -hydroxy-5 $\alpha$ -androstan-17-one or 16 $\alpha$ -bromodehydroepiandrosterone.
9.        The method of claim 1 wherein the subject is coinfecting with a retrovirus.

10. The method of claim 10 wherein the subject is a human, a primate or a feline and the retrovirus is HIV1, HIV2, SIV, SHIV or FIV.

11. The method of claim 1 wherein the formula 1 compound has the formula 1B or 1C



wherein,

each R<sub>1</sub> independently is -H, -OH, a halogen, -CHCH<sub>2</sub>, -CHCHCH<sub>3</sub>, -CCH, -CCCH<sub>3</sub>, or, together with the hydrogen atom that is bonded to the same carbon atom comprises =O;

R<sub>2</sub> is -O-C(O)-R<sub>4</sub>, -S-C(O)-R<sub>4</sub>, -O-S(O)(O)-R<sub>4</sub>, -O-S(O)(O)-OR<sub>4</sub>, -O-C(O)-NHR<sub>4</sub>, or -O-C(S)-R<sub>4</sub>;

R<sub>4</sub> is -H, a protecting group, optionally substituted C<sub>1-18</sub> alkyl, optionally substituted C<sub>1-18</sub> alkenyl, optionally substituted C<sub>1-18</sub> alkynyl, optionally substituted aryl, optionally substituted aryl-C<sub>1-6</sub> alkyl, optionally substituted aryl-C<sub>2-6</sub> alkenyl, optionally substituted aryl-C<sub>2-6</sub> alkynyl, optionally substituted heterocycle-C<sub>1-6</sub> alkyl, optionally substituted C<sub>2-6</sub> alkenyl-heterocycle, optionally substituted C<sub>2-6</sub> alkynyl-heterocycle or an optionally substituted heterocycle, where any of the foregoing moieties are optionally substituted at one, two, three, four, five or more carbon or hydrogen atoms with one or more independently selected -O-, -S-, -NR<sup>PR</sup>-, -OR<sup>PR</sup>-, -NHR<sup>PR</sup>-, -SR<sup>PR</sup>-, =O, =S, -CN, -NO<sub>2</sub>, -F, -Cl, -Br or -I groups or atoms; and

each R<sup>PR</sup> independently is -H or an independently selected protecting group;

20 Q<sub>2</sub> is -C(R<sub>1</sub>)<sub>2</sub>-; and

Q<sub>3</sub> and Q<sub>6</sub> independently are -H, -CH<sub>3</sub> or -CH<sub>2</sub>OH.

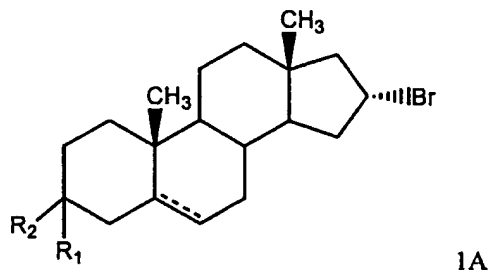
12. The method of claim 11 wherein Q<sub>3</sub> and Q<sub>6</sub> are both -CH<sub>3</sub> in the β-configuration;

and

Q<sub>2</sub> is -CH<sub>2</sub>-, -C(O)-, -CH(Br)-, -CH(I)-, or -CH(OH)- with the Br, I or OH moieties in the  
25 α-configuration, or Q<sub>2</sub> comprises -C(O)- or -CH<sub>2</sub>-CH<sub>2</sub>-; and

R<sub>1</sub> at the 7-position is -H, -OH or, when taken with the hydrogen atom that is bonded to the same carbon atom, R<sub>1</sub> is =O.

13. The method of claim 1 wherein the formula 1 compound has the formula 1A



wherein,

R<sub>2</sub> is -OH, halogen, C<sub>1-6</sub> alkoxy, -OR<sub>3</sub>, a C<sub>1-18</sub> fatty acid, C<sub>1-10</sub> alkynyl, (J)<sub>n</sub>-phenyl-C<sub>1-5</sub>-alkyl, (J)<sub>n</sub>-phenyl-C<sub>1-5</sub>-alkenyl, an ester optionally selected from -O-C(O)-(CH<sub>2</sub>)<sub>m</sub>-R<sub>4</sub> and -C(O)-O-(CH<sub>2</sub>)<sub>m</sub>-R<sub>4</sub>, or R<sub>2</sub> is -S-C(O)-(CH<sub>2</sub>)<sub>m</sub>-R<sub>4</sub>, -C(O)-S-(CH<sub>2</sub>)<sub>m</sub>-R<sub>4</sub>, -O-S(O)(O)-(CH<sub>2</sub>)<sub>m</sub>-R<sub>4</sub>, -O-S(O)(O)-O-(CH<sub>2</sub>)<sub>m</sub>-R<sub>4</sub>, -O-C(O)-NH-(CH<sub>2</sub>)<sub>m</sub>-R<sub>4</sub>, -NH-C(O)-O-(CH<sub>2</sub>)<sub>m</sub>-R<sub>4</sub>, -O-C(S)-(CH<sub>2</sub>)<sub>m</sub>-R<sub>4</sub>, -C(S)-O-(CH<sub>2</sub>)<sub>m</sub>-R<sub>4</sub>, -O-C(O)-(CH<sub>2</sub>)<sub>m</sub>-R<sub>4</sub> or -C(O)-O-(CH<sub>2</sub>)<sub>m</sub>-R<sub>4</sub>, or R<sub>2</sub>, together with the R<sub>1</sub> group that is bonded to the same carbon atom is =O;

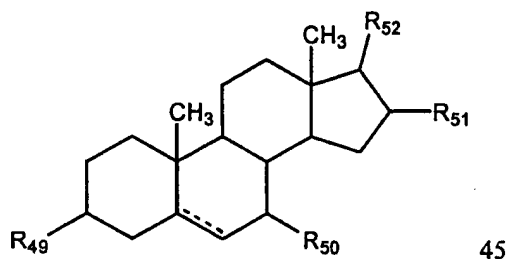
R<sub>4</sub> is -H, a protecting group, optionally substituted C<sub>1-18</sub> alkyl, optionally substituted C<sub>2-18</sub> alkenyl, optionally substituted C<sub>2-18</sub> alkynyl, optionally substituted aryl, optionally substituted aryl-C<sub>1-6</sub> alkyl, optionally substituted aryl-C<sub>2-6</sub> alkenyl, optionally substituted aryl-C<sub>2-6</sub> alkynyl, optionally substituted heterocycle-C<sub>1-6</sub> alkyl, optionally substituted C<sub>2-6</sub> alkenyl-heterocycle, optionally substituted C<sub>2-6</sub> alkynyl-heterocycle or an optionally substituted heterocycle, where any of the foregoing moieties are optionally substituted at one, two, three, four, five or more carbon or hydrogen atoms with one or more independently selected -O-, -S-, -NR<sup>P</sup>PR-, -OR<sup>P</sup>PR-, -NHR<sup>P</sup>PR-, -SR<sup>P</sup>PR-, =O, =S, -CN, -NO<sub>2</sub>, -F, -Cl, -Br or -I groups or atoms;

each R<sup>P</sup>PR independently is -H or an independently selected protecting group;

m is 0, 1, 2 or 3; and

the dotted line is an optional double bond.

14. The method of claim 1 wherein the formula 1 compound has the formula 45



wherein,

R<sub>50</sub> is -H, -OH or =O;

R<sub>51</sub> is -Br, -Cl, -F, -I or -OH;

R<sub>52</sub> is -OH or, R<sub>52</sub>, together with the -H bonded to the same position, is =O;

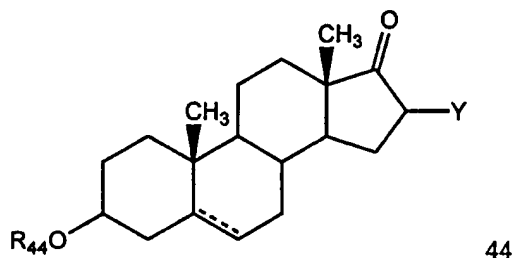
R<sub>49</sub> is -H, -OH, or -OR<sub>53</sub>;

R<sub>53</sub> is C<sub>1-18</sub> alkyl, C<sub>2-18</sub> alkenyl, C<sub>2-18</sub> alkynyl, a C<sub>1-18</sub> ester, a C<sub>1-18</sub> thioester, wherein any of the foregoing C<sub>1-18</sub> or C<sub>2-18</sub> groups is substituted at one or more hydrogen atoms with one or more independently selected -O-, -S-, -OH, -NH<sub>2</sub>, -SH or =O groups or R<sub>53</sub> is a thioacetal, a sulfate ester, a sulfonate ester, a carbamate or a thioester; and

the dotted line is an optional double bond.

15. The method of claim 14 wherein R<sub>49</sub> is -O-C(O)-CH<sub>2</sub>-CH<sub>2</sub>-CH(R<sub>54</sub>)-CH(R<sub>55</sub>)-CH<sub>2</sub>R<sub>56</sub> wherein R<sub>54</sub> is -NH<sub>2</sub>, -OH, -SH, -O-PO<sub>3</sub>, -SO<sub>3</sub> or -OSO<sub>3</sub>; R<sub>55</sub> is -H, -NH<sub>2</sub>, -OH, -SH, -O-PO<sub>3</sub>, -SO<sub>3</sub> or -OSO<sub>3</sub>; and R<sub>56</sub> is C<sub>1-18</sub> alkyl, C<sub>2-18</sub> alkenyl, C<sub>2-18</sub> alkynyl, a C<sub>1-18</sub> ester or a C<sub>1-18</sub> thioester, wherein any of the foregoing C<sub>1-18</sub> or C<sub>2-18</sub> groups is substituted at one or more hydrogen atoms with one or more independently selected -OH, -NH<sub>2</sub>, -SH or =O groups.

16. The method of claim 1 wherein the formula 1 compound has the formula 44



wherein,

- 15 Y is hydrogen or a halogen;

R<sub>44</sub> is -H, -S(O)(O)-OH, -S(O)(O)-ONa, -S(O)(O)-O-CH<sub>2</sub>-CH(O-C(O)-R<sub>6</sub>)-CH<sub>2</sub>-O-C(O)-R<sub>6</sub>, -P(O)(O)-O-CH<sub>2</sub>-CH(O-C(O)-R<sub>7</sub>)-CH<sub>2</sub>-O-C(O)-R<sub>7</sub> or a glucuronide group of structure (A); and

the dotted line is an optional double bond.

- 20 17. The method of claim 16 wherein the formula 44 compound is dehydroepiandrosterone, epiandrosterone, 16 $\alpha$ -bromoepiandrosterone, 16 $\alpha$ -bromodehydroepiandrosterone, dehydroepiandrosterone-3-sulfate or 5 $\beta$ -androstane-3 $\beta$ -ol-17-one.

18. The method of claim 17 wherein the formula 44 compound is 16 $\alpha$ -bromoepiandrosterone.

- 25 19. A method comprising (1) contacting a formula 1 compound and polyethylene glycol to obtain a mixture, (2) vortexing the mixture to form a smooth liquid, (3) contacting additional propylene glycol to the smooth liquid and vortexing to form a uniform suspension, (3) contacting benzyl benzoate with the uniform suspension and vortexing to form a liquid, (4) contacting ethanol with the liquid and vortexing to form a solution; and (5) optically contacting the solution more propylene glycol to form a formulation.

20. The method of claim 19 wherein the formula 1 compound is dehydroepiandrosterone, epiandrosterone, 16 $\alpha$ -bromoepiandrosterone, 16 $\alpha$ -bromodehydroepiandrosterone, dehydroepiandrosterone-3-sulfate or 5 $\beta$ -androstane-3 $\beta$ -ol-17-one.

21. The method of claim 20 wherein the formula 1 compound is 16 $\alpha$ -  
5 bromoepiandrosterone.

22. The method of claim 21 wherein the formulation comprises about 40-60 mg/mL 16 $\alpha$ -bromoepiandrosterone.

23. The method of claim 22 wherein the formulation comprises about 50 mg/mL 16 $\alpha$ -bromoepiandrosterone, about 25% polyethylene glycol 300 v/v, about 12.5% dehydrated ethyl  
10 alcohol v/v, 5% benzyl benzoate v/v, and 57.5% propylene glycol v/v.

24. A composition comprising about 90-110 mg/mL of 16 $\alpha$ -bromoepiandrosterone, about 27-33% benzyl benzoate w/w, about 28-34% polyethylene glycol 300, about 25-31% w/w, propylene glycol, and about 1-3% w/w benzyl alcohol.

25. The composition of claim 24 comprising about 100 mg/mL of 16 $\alpha$ -  
15 bromoepiandrosterone, about 30.4% benzyl benzoate w/w, about 30.7% polyethylene glycol 300, about 28% w/w, propylene glycol, and about 1.9% w/w benzyl alcohol.

26. A method to treat or prevent a *Toxoplasma* or *Cryptosporidium* infection, or to ameliorate one or more symptoms associated with a *Toxoplasma* or *Cryptosporidium* infection, in a subject suffering from or subject to a *Toxoplasma* or *Cryptosporidium* infection, comprising  
20 administering to the subject an effective amount of a composition comprising 16 $\alpha$ -bromoepiandrosterone, and 2, 3, 4 or 5 excipients selected from polyethylene glycol, dehydrated ethanol, benzyl benzoate, benzyl alcohol and propylene glycol, wherein the composition optionally comprises less than about 3% v/v, or less than about 1% v/v, or less than about 0.5% v/v of water, or less than about 0.1% v/v of water.

25 27. The method of claim 26 wherein the composition comprises 16 $\alpha$ -bromoepiandrosterone at a concentration of about 45-55 mg/mL, 20-30% v/v polyethylene glycol 300, polyethylene glycol 400 or a mixture of polyethylene glycol 300 and 400, 10-15% v/v dehydrated ethyl alcohol, 2.5-7.5% v/v benzyl benzoate, and 55-60% v/v propylene glycol.

28. The method of claim 27 wherein the composition comprises 16 $\alpha$ -  
30 bromoepiandrosterone at a concentration of about 50 mg/mL, about 25% v/v polyethylene glycol 300, about 12.5% v/v dehydrated ethyl alcohol, about 5% v/v benzyl benzoate, about 57.5% v/v propylene glycol and less than about 0.5% v/v water.

29. The method of claim 26 wherein the composition comprises 16 $\alpha$ -bromoepiandrosterone at a concentration of about 85-105 mg/mL, about 27-33% w/w benzyl

benzoate, about 27-33% w/w polyethylene glycol 300, about 25-30% w/w propylene glycol and about 1-3% w/w benzyl alcohol.

30. The composition of claim 29 wherein the composition comprises 16 $\alpha$ -bromoepiandrosterone at a concentration of about 100 mg/mL, about 30.4% w/w benzyl benzoate, about 30.7% w/w polyethylene glycol 300, about 28% w/w propylene glycol and about 1.9% w/w benzyl alcohol.

31. The method of claim 1 wherein 2, 3, 4, 5 or 6 R<sub>1</sub> are not hydrogen.

32. The method of claim 31 wherein the 2, 3, 4, 5 or 6 R<sub>1</sub> that are not hydrogen are independently selected from -OH, =O, halogen and C<sub>2-4</sub> alkoxy.